UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters Products Liability Litigation	MD-15-02641-PHX-DGC
	Phoenix, Arizona
	December 15, 2017

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

MOTION HEARING

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P R O C E E D I N G S

THE COURTROOM DEPUTY: In the matter of MDL 2015-2641, Bard IVC Filters Products Liability Litigation, on for motion hearing.

Will the parties please announce.

MR. LOPEZ: Good afternoon, Your Honor. Ramon Lopez on behalf of Plaintiffs' Leadership Committee.

MR. O'CONNOR: Your Honor, Mark O'Connor for Plaintiffs' Leadership Committee.

MR. ARBITBLIT: Your Honor, Donald Arbitblit for Plaintiffs' Leadership Committee.

MS. SMITH: Your Honor, Laura Smith for Plaintiffs' Leadership Committee.

THE COURT: All right. Good afternoon.

MR. ROTMAN: Steve Rotman, Plaintiffs' Steering Committee.

MS. O'LEARY: I'm Leslie O'Leary. I'm not part of the Plaintiffs' Steering Committee, but I'm going to be arguing a motion today, and I've been admitted pro hac vice.

MR. NORTH: Good afternoon, Your Honor. Richard North on behalf of defendants, and I'm joined by Jim Condo and my partners James Rogers, Matthew Brown, and Elizabeth Helm.

THE COURT: All right. Good afternoon.

MULTIPLE VOICES: Good afternoon, Your Honor.

THE COURT: All right. We are going to be addressing today the motion to disqualify Dr. Kinney; the motion to disqualify Drs. Resnick, Vogelzang, and Desai; the motion to exclude Dr. Parisian; the motion to exclude Dr. Kessler; and the motion to exclude Kinney, Roberts, and Kalva. Those are the five motions that we've got teed up for today.

What I want to talk to you about as well today is the timing for the rest of the expert motions that are still pending; I want to talk about trial scheduling issues in terms of amount of time and specific day issues I've got in March just so we can work around them; and I want to talk about the defendants' motion to certify the preemption ruling for appeal.

I understand that some of you, I think Mr. Condo and Mr. Lopez, need to leave by 3:00 or a little bit after. I'm hoping we're done by then, I'm not sure we'll need more time, but to make sure we cover what is most important while you gentlemen are here, is there anything in particular you want to take up first?

MR. LOPEZ: Not from my -- everything else is covered, Your Honor, with respect to what's on the Court's calendar.

THE COURT: Okay.

MR. LOPEZ: So I'm fine.

MR. NORTH: Your Honor, we're at the Court's

discretion as well.

THE COURT: Okay. All right.

Let's talk first, then, about the motions to disqualify Dr. Kinney and Drs. Resnick, Vogelzang, and Desai. It's the same issue, in effect, with respect to the experts.

On all of these motions I've read the briefs, I've read relevant exhibits. When it comes to experts, I've read portions of the expert reports; I've not read them all. Nor could I, I don't think. I tried to read relevant cases. I haven't read all of the cases the defendant cites on a portion of the fifth motion about what an expert can or can't say on a reasonable physician's view. There's a long string, so I want to read those cases.

My point is I'm pretty familiar with what the issues are and arguments are. You don't need to walk me through the basics. I'm really most interested in what you think are the key points now that the briefing is done.

So let's start with those two motions to disqualify and take those together.

MR. NORTH: Your Honor, Ms. Helm will present argument on those.

THE COURT: All right.

MS. HELM: Thank you, Your Honor.

As the Court has recognized, the basic law is the same as -- almost as the same as it relates to these two

motions and the courts have applied two tests. Either the bright-line test or the two-part test. And I think the issue under both of those tests, based on the briefing, is whether the expert -- and I'm going to start with Dr. Kinney -- received confidential information.

Under the bright-line test there's no question that Dr. Kinney was retained by Bard in IVC filter litigation.

Under the two-part test, there's no question that Dr. Kinney was retained by Bard in IVC filter litigation and that Dr. Kinney had multiple consulting agreements with Bard that included confidentiality provisions. So under the two-part test there doesn't seem -- the plaintiffs don't challenge that there were confidential relationships under each test.

So the question becomes, under the bright-line test, did he receive confidential information? And under the two-part test, did he receive confidential information? If he did, he has a conflict.

And our position is that he in fact did receive confidential information. The plaintiffs' position is that he did not receive confidential information that is relevant to this litigation. And so I'm going to address what confidential information that he did receive and what evidence the Court has.

One thing I think is important to note with

Dr. Kinney, in his report he lists as one of his qualifications -- the report is broken down in different categories and they have their qualifications, and he lists as his qualification the fact that he has done consulting work with Bard.

He then, now that we have filed a motion raising that very issue, tries to back off of it and say, oh, no, no, no, it was nothing important, I didn't do anything. But it was important enough for him to list it as a qualification.

When he was retained by counsel he was retained and had conversations with Mr. North in the two cases in which he was retained.

In at least one of the cases Mr. North made the decision of what documents to send to him and what opinions Mr. North wanted him to evaluate and give in the case. That in and of itself right there is work product. The choice of what documents to provide to an expert, the choice of discussing what opinions the expert should or should not offer is work product. Everyone in this litigation has taken that position as it relates to the experts. Except in the context of this motion they're saying, no, no, no, I didn't get any work product.

More importantly, if you look at what Dr. Kinney did when he was consulting with Bard, he touched in the very areas that they criticize in the expert report. He touched in

testing. He was involved in testing of IVC filters. The very filters that are at issue in this case. We then have a report that says Bard didn't adequately test their filters.

He was involved in analysis of adverse events, responding to adverse events. Then we have an opinion that says Bard didn't adequately respond to adverse events.

He was involved in analysis of failure modes of filters. He had a conversation with the president of Bard Peripheral Vascular about failure modes of filters and what was going on and the complications that could come from that that was then incorporated in an analysis of the filters.

In their expert report, they challenge failure modes. Bard didn't do enough, Bard didn't analyze what was going on with the filters. His very work as a consultant. He was provided test protocols. They challenge testing. He was provided and discussed information regarding adverse events. They challenge adverse event analysis. He was involved in discussion of failure analysis. They say Bard didn't do enough.

He was involved and received information from the company on very areas on which they opine in their report.

Dr. Kinney -- we don't have to show -- for the conflict to exist, we don't have to show that he used that information or that he relayed it to other people. He has a conflict. And we believe because of that conflict, because he

received confidential information, which is the second prong on whichever test the Court chooses to apply, because he had that confidential information, he had the conflict. He should have never been involved in this litigation.

And interestingly, he didn't report, at least in the report and it appears plaintiffs' counsel didn't know that he had prior -- previously been retained by Nelson Mullins to serve as an expert until our motion was filed.

He mentioned his prior consulting in his report but did not mention his prior employment as a medicolegal expert for Nelson Mullins.

Dr. Kinney received confidential information. Dr. Kinney has a conflict.

We are not seeking to exclude Dr. Kalva or Dr. Roberts because through Dr. Kinney's testimony we're able to delineate what he did. He testified about what portions of the report he wrote and what portions of the report the other doctors were involved in. So they can still testify. We're not trying to impugn, and frankly we don't have the evidence to impugn his conflict to them, so we are not seeking to exclude Dr. Roberts or Dr. Kalva. That's what makes the two situations a little different.

The plain evidence before the Court is he sat down either by telephone or in person and met with the defense lawyer who made decisions about what information to provide

him. He received that information and provided information back to -- in the form of a draft report back to defense counsel. All of that falls into the very definition of work product.

He consulted with the company. He received test protocols. He received confidential internal information that's not available outside to the public. And he did it not once, not twice, but he did it six times. He had six different consulting agreements relating to IVC filters.

Dr. Kinney has a conflict. Dr. Kinney should not be involved in this litigation and the plaintiffs should be allowed to go forward with Dr. Roberts and Dr. Kalva.

Do you want me to go ahead and address the other one?

THE COURT: Let me ask you one question first. You've just described what -- you've just described what Mr. North did and shared with Dr. Kinney. There's no declaration or affidavit in the record regarding that, is there?

MS. HELM: No, Your Honor, there's no declaration in the record. Mr. North is here. He can state in his place. Dr. Kinney actually admits that he received certain information from Mr. North. So even using Dr. Kinney's declaration, it's in the record that he received information from defense counsel.

THE COURT: Okay. Why don't you address the other

motion.

MS. HELM: Your Honor, we have the same test to start with, with Dr. Resnick. A little bit of -- what makes this one a little bit different is a couple things. Number one, I'm going to refer to them as the Northwestern doctors rather than stumbling over each of their names. The Northwestern doctors made a decision to create an entity. A legal entity. They're operating under an entity node as SBBK. They're all four equal partners in this legal entity. The entity is who bills for the work that they did. The entity has some sort of a tax ID number or W-9, because if you look at the invoices they're all in the name of the entity SBBK Consultants LLC.

So you don't have three independent doctors doing their work and getting paid for what they do, you have four doctors that have formed one entity.

Regardless of how much each of them works, they're going to split the profits one fourth, one fourth, one fourth. That's been testified to by Dr. Vogelzang.

And what you have here is a situation where Dr. Resnick, again, should have never been involved. Dr. Resnick was retained as an expert witness in a Bard case after this MDL was filed. He met with Mr. Rogers in 2015 for three hours in a case that's not in the MDL but after the MDL was pending and filed.

Mr. Rogers, and he admits it in his declaration,

Mr. Rogers chose what information to provide to him and what information he wanted him to review.

Again, Mr. Rogers made a work-product decision of what information to provide to Dr. Resnick and provide it to him. Dr. Resnick also previously served as a consultant for Bard. Obviously Bard is talking to doctors who had previously worked for the company as consultants as potential experts. We're not out trying to conflict out interventional radiologists where you -- working with people who had worked with the company before.

Dr. Resnick did not tell plaintiffs' counsel he had been retained by Bard and apparently didn't tell plaintiffs' counsel he had consulted with Bard. Plaintiffs' position in their papers is they learned it when we filed the motion. And they have admitted that he shouldn't be involved, because they've taken the position in their papers that -- to use their term, they've walled him off. They have told the other three Northwestern doctors not to consult with him any more.

If there was no problem with Dr. Resnick's involvement, if he didn't -- if he had not been exposed to confidential -- and received confidential information, there was no need to wall him off.

Plaintiffs implicitly admit that there's a problem there and admit -- and they're going to say it was boots and suspenders. But if there's no problem, why take him out? The

prob- -- and, in fact, the problem is they took him out too late.

If you look at what Dr. Resnick did, he met with Mr. Rogers for three hours about a case that was pending in 2015. He received information that Mr. Rogers chose to send to him. This is all in Dr. Resnick's deposition, and Mr. Rogers can state it in his affidavit or declaration. Mr. Rogers can state it in his place.

If you look at the consulting he did, he was likewise involved in testing of filters. Directly involved in the kind of work and the kind of issues that are in this case.

Here's the difference, though: The Northwestern doctors, the SBBK report, is, as Dr. Vogelzang testifies at length in his deposition, a collaborative report. Dr. Vogelzang cannot tell you who wrote what or who did what.

Dr. Resnick testifies in his declaration that his role was modest. That's his word that he uses in paragraph 8 of his declaration.

But Dr. Vogelzang's own testimony is contradicted by the invoices from SBBK.

The other thing that's very important is Dr. Vogelzang testified, and Dr. Desai testified, that it's Dr. Resnick who wrote the invoices. He was in charge of the billing.

So Dr. Resnick's own invoices show that he was

involved in every aspect of the work that these -- the SBBK doctors did, except one phone call. There's one phone call that was Dr. Vogelzang alone.

Every other entry has Dr. Resnick involved and there's at least one entry where he's the sole person who billed for the work.

So unlike Drs. Kinney, Kalva, and Roberts where you can parse out, frankly, based on their testimony who did what, in this case it is, to use Dr. Vogelzang's own testimony, it is a collaborative effort and you cannot divide out what Dr. Resnick influenced, what he didn't, what Dr. Resnick wrote and what he didn't. And it was interesting because Dr. Vogelzang seemed to want to emphasize that because he said it over and over again, and he said "This was a collaborative effort, I cannot say who did what." Dr. Resnick contributed to every aspect in some part.

So we have a situation here where we have an entity where these four doctors have chosen to make themselves an entity, where the entity has a part of it Dr. Resnick, who the plaintiffs admit was involved in confidential relationships with Bard and who his own testimony shows received confidential information, even more so while the MDL was pending. And you can't -- there's no way to, using the doctors own testimony, to parse out and say, well, Resnick was involved in this or he wasn't involved in that.

Resnick's a non-testifying -- he's a consulting expert who had his hands in everything. And so there's no way to resolve this for Bard or to avoid the conflict without disqualifying the entity as a whole. As opposed to trying to parse it out. Dr. Vogelzang makes that impossible because, frankly, it was a collaborative effort.

And plaintiffs are going to argue again that there's prejudice and that the Court shouldn't do this because they're prejudiced if they lose Dr. Desai and Dr. Vogelzang, who are the testifying witnesses.

Plaintiffs still have Dr. Kinney and Dr. Roberts as interventional radiologists. These are all interventional radiologists. There's also another interventional radiologist who is designated and has testified in all of the bellwether cases in Dr. Hurst. So the plaintiffs are not left without a medical doctor in that area of expertise in these cases.

The flip side of it is if these three -- if those four doctors and Dr. Kinney are left in, Bard is faced with experts who have Bard -- had Bard confidential information with whom Bard had anticipated and expected confidential relationship, documented in writing through various consulting agreements, who have now testified -- who are now either testifying or participating in testifying against the company.

Through the judicial balance and the integrity of the system, we believe that the right thing to do is to disqualify

Dr. Kinney, let Dr. Roberts and Dr. Kalva go forward, pending the *Daubert* motion on them, but the entire SBBK doctors should all four be disqualified.

Thank you.

THE COURT: Okay. Thank you.

MR. ROTMAN: May it please the Court. Good afternoon, Your Honor.

THE COURT: Good afternoon.

MR. ROTMAN: I'm Steve Rotman and I will be addressing the Northwestern Group on the facts and the legal standards for all of the disqualification issues, and then Laura Smith will be addressing the specific facts and arguments relating to Dr. Kinney.

I'd like to start by a housekeeping matter. Yesterday for the first time, in looking over the papers, I realized that it was possible that we never filed the Resnick declaration. So we filed it yesterday. It wasn't clear, but out of abundance of caution, we filed it yesterday. The reason it wasn't clear is because in looking at the defense briefs, they responded to comments in the Resnick declaration. Perhaps we served it and didn't file it. Perhaps we did both. But the record wasn't clear. So now, Your Honor, we just want to make sure it's part of the record. We did refer to it in our brief, in our opposition brief. I have a copies of it with me, hard copies of it with me here today, so I can also

provide a copy to Your Honor --

THE COURT: There's no need. Thank you.

MR. ROTMAN: -- if there's any need for that.

I'd like to start by just giving an overview of some important issues that were perhaps not clear and would not be clear to the Court from reading the defendants' brief.

Although Bard cited four times to the *Hewlett Packard* case, which is a case decided by the Northern District of California, part of the Ninth Circuit, cited four times in their initial brief, there's -- there's important legal standards in the *Hewlett Packard* case that govern how the Court should be thinking about both motions. I will start by pointing out that the court stated the following: That disqualification is a drastic measure that courts should impose only hesitantly, reluctantly, and rarely.

They go on and say -- talk about the two-prong test that is in -- that is in the briefs, but they make the point that the two prongs are both separate and distinct and you must prove both.

You can't prove one and then presume the second one. You can't assume the second one or bootstrap to the second one from proving the first. So if you prove that there was a confidential relationship, you can't just assume that there was confidential information transferred. And the confidential information has got to be a particular type of

confidential information, protected information, the type that is work product, attorney client, not discoverable, and related to the specific case.

THE COURT: Are you saying only work-product and attorney-client privileged materials counts?

MR. ROTMAN: Those are -- I'm not saying -- that's what the court said in *Hewlett Packard*.

THE COURT: Doesn't it begin the statement by saying "Information of particular significance or attorney-client work product"? I mean "attorney work product."

MR. ROTMAN: You might be correct on that, Your Honor.

So -- so we need to have -- the other thing that's clear from reading this case as well as all the others is that the burden's on the moving party. So our main point here today is that they have to prove both prongs and they have the burden. And there's no presumption or assumption. There needs to be specific proof. There wasn't any provided for prong number 2.

Let's just look at Dr. Vogelzang. There's no evidence of any confidential relationship, that's prong one, nor any evidence that he received confidential information. All of the evidence relates to Dr. Resnick. We took Resnick off the table. Not because we were admitting that he should be disqualified, because we could be standing here arguing

about Dr. Resnick and make the argument they haven't met their burden that any confidential information was ever provided to him.

Yes, he had a -- there was a potential for confidential relationship in that three-hour meeting, but he submitted a declaration, as did Drs. Vogelzang and Desai, saying they never received any confidential information from him, and his declaration states he never provided any to them nor did he receive any. He had a three-hour meeting in which they provided him medical records of a plaintiff. That's not confidential to us. We have the same medical records. It's our client, this woman, this plaintiff, in the Austin case. The medical literature, their own experts provide their medical literature along with their expert reports. That's not protected confidential information that gives us any advantage.

If I go to any -- any one of several of their expert reports and flip to the section on materials relied on and citations and references, I get over 170 papers cited.

So in -- whereas Dr. Resnick, Vogelzang, and Desai submitted declarations denying that there was confidential information, whether or not you call that meeting of three hours a confidential relationship, there was nothing from Bard. No declaration.

Now, the fact that Mr. Rogers is here today is a

little bit late. We wrote our brief, we wrote our opposition. They had plenty of opportunity to submit.

We wrote in our opposition they hadn't met their burden. They did a reply brief. They had an opportunity at that time.

In addition, for Vogelzang -- and on the Vogelzang issue, they took the deposition of Drs. Vogelzang and Desai. They didn't ask for the deposition of Dr. Resnick. And asked neither one of them in two-full day depositions any questions at all about what information Dr. Resnick did or did not provide to them that came out of any prior confidential relationship.

They want the Court to presume that there was confidential information because there was the opportunity for it. But they provide no specifics, no declaration. They didn't inquire in their opportunity to do so to develop a record, and so their burden is not met.

In addition, Your Honor, in the Vogelzang Northwestern doctors situation, they received notice on March 2nd in the initial report and then two additional reports after that, later in March and then in April, all making it clear that Resnick was a part of the collaboration with Vogelzang and Desai. And yet they did not provide a letter notifying us of any concern about conflict until June 29, after it was too late for us to do anything other than spend a

considerable amount of money on these experts' fees and time and resources developing three expert reports, preparing them for their deposition, and at a point in which it's then too late for us to name any other alternative experts or rebuttal experts.

So they had all the information they needed on day 1, March 2nd, to know that Resnick was involved.

In the Kinney case, 12 days after they received the Kinney report they wrote such a letter. But in the Northwestern Group case, nothing came until June 29.

So what happened with Resnick is on the meeting in October of 2015 that lasted about three hours, they talked about they had about 50 cases they might get him involved in. In this particular meeting in which his declaration states he was not provided any insight into legal strategies, legal defense strategies, and so forth, he did impart to Mr. Rogers, who was the lawyer from Nelson Mullins that met with him, what he thought about the Bard filters. Critical of the Bard filters. And he told -- and his declaration states that he never heard from them again.

All through 2016, when this litigation was in full throttle and Bard was naming a number of experts on a number of different cases, Resnick was not part of that.

So I question whether there was a confidential relationship, even prong one, with Resnick. It looks more

like it was a screening interview. They were feeling him out. They were interviewing him. They were trying to decide, was he going to be one of their experts? He told them something they didn't want to hear, his opinion about their design, their filter design, and his experience with their filters being problematic. The meeting ended and they never heard from him again.

When we hired Vogelzang, he told us he works with this group. He never mentioned to us, because he didn't know, about this meeting in October of 2015. And when we learned about it after they filed their motion, wrote their letter filed their motion, I asked Resnick, why didn't you tell us? He said he didn't even remember it. He didn't -- it didn't -- that was just -- that was how significant it was, this three-hour meeting.

So we have -- and there's language, by the way, in this *Hewlett Packard* case about how the courts want to be vigilant about the situation where potential experts at a nominal fee will be disqualified by having meetings such as this one.

THE COURT: You've talked all about that three-hour meeting. He was a consultant with Bard between 2003 and 2014; right?

MR. ROTMAN: He was. And as he states in his declaration, most of that had nothing to do with IVC filters.

THE COURT: But are you disputing there was a confidential relationship? That seems to be what you're arguing with respect to Dr. Resnick.

MR. ROTMAN: What I'm arguing about Resnick is that we don't have to spend time on Resnick because we took him out.

THE COURT: That's fine. We just spent a lot of time on him and I wasn't quite sure --

MR. ROTMAN: Well, I spent time on him because they want to bootstrap from Resnick to Vogelzang and Desai and Lewandowski. They have to prove prong 1 and prong 2 for Vogelzang and Desai and Lewandowski. And so where was the confidential relationship with each of those three, and where's the evidence from Bard there was not only a confidential relationship with each of them but that each of them received confidential information from Resnick? Which they deny and he denied, and they only put it in a brief that confidential information was provided to Resnick, but they have no idea whether, if that -- if that is even true whether he then transferred that information to Vogelzang and Desai and Lewandowski, and the Court cannot presume that. Is it possible? That's not the standard. Remember what the court said, it's a drastic remedy and stringent burden. Courts are very reluctant and very demanding. It's not nonchalant to cross over the specific requirements and the burdens.

I'm going to pass to Ms. Smith who will address the other experts.

THE COURT: Okay.

MS. SMITH: Good afternoon, Your Honor. I have a brief PowerPoint presentation to go along with my argument. Is that all right?

THE COURT: Sure.

MS. SMITH: Your Honor, I'm here to discuss Dr. Kinney's motion regarding disqualification. My name is Laura Smith.

First and foremost, what I want to point out is Bard has not met their burden. They have provided no evidence there was actual confidential relationship that is relevant to the current litigation and that is not subject to discovery that's already been issued in this litigation. They have not provided any documents, they've not provided any description of information.

Furthermore, when they found out that Dr. Kinney was one of plaintiffs' experts they did send us a letter. I have a copy of the letter here. And initially we asked them right away to send us information about Dr. Kinney and if he was exposed to confidential information, please let us know, and to give us some of that -- to provide us with the information so that we could then make an assessment of whether we believed it was confidential and we could move forward.

There was an opportunity in the very beginning to mitigate this and the defendants never provided any information. This was back in March of 2- -- March 22nd, 2017.

You can see here we have a follow-up letter and even at Dr. Kuo's deposition, Ramon spoke to the attorney there and asked him to provide this information to us.

If they're going to accuse Dr. Kinney of switching sides, which is such a serious allegation, they could then provide us with what confidential information he had been disclosed with.

They never even mention the manner in which they give it to Dr. Kinney. There was no request for in-camera review. There's been no declaration from Bard, although there was an assertion that Mr. North would be willing to make that today. And even furthermore, in the expert report they have not identified any portions of it that they believe came from confidential information that Dr. Kinney received while he was an expert. I'm sorry, while he was a consultant for Bard.

After Dr. Kinney's deposition, they did not supplement their motion with any information and at this point Bard provided nothing but vague statements.

As I said, Bard has not met their burden. Today I'm focusing on the second prong of the part 2 test. The bright-line test tends to apply when there's more of a clear

and blatant side switching, and then when there's a dispute the courts tend to apply the two-part test.

We are not arguing about the confidential relationship, but we are arguing that no confidential information that is relevant to this litigation that merits disqualification was disclosed to Dr. Kinney.

One thing is clear, is that courts do require that parties provide concrete, hard evidence. They're not willing to look at vague and ambiguous statements, and they need to represent it with specific facts. And here, as I said, Bard has yet to provide this evidence.

Furthermore, Bard noticed Dr. Kinney's deposition two months after receiving their motion, after filing this motion to disqualify. At that deposition they had the perfect opportunity to ask Dr. Kinney any kind of questions that would relate to this. They had the opportunity to get the actual evidence that they needed, and they chose not to. Dr. Kinney even provided his report of Mattes at the litigation, his summary, medical summary. He had it there with him. And I have it here today. We offered it for in-camera review so it can be very clear the type of information he was looking at was only from medical records, and you can see that there's no other discussion within those papers than medical records.

One thing the plaintiffs have done, because there is conflicting information here, is we have provided the Court

with a sworn declaration from Dr. Kinney, and Dr. Kinney has testified under oath. Courts have found that a sworn declaration is sufficient to alleviate any concerns and deny a motion for disqualification.

Further, courts have also found at this late stage that in order for the parties not to suffer a hardship, the expert -- for an expert to be disqualified, they can rely on an expert's declaration.

Here is a copy of the declaration. I know it was an exhibit and you have reviewed it, but one part I would like to emphasize is that Dr. Kinney states, "The work I performed for the plaintiffs is not based on any information I derived or received when I was a consultant for Bard. The expert report where I list documents, data, information, facts I considered for my opinions, none of which I reviewed when I was a consultant. In fact, I was not even aware of the existence of this material."

So here we have Bard's assertions that when Dr. Kinney -- when Dr. Kinney worked for them as a consultant for two and a half years about ten to 12 years ago, they claim he received confidential information that is relevant to this litigation.

Dr. Kinney, from the agreements that we've seen, he helped implant and teach doctors how to implant and remove filters. He did work in a lab under two animal studies, which

Elizabeth Helm mentioned. In that he recorded data. He never got to see the results. He never was a party to making decisions about those results. He merely was acting as a lab assistant.

Further, when Dr. Kinney worked on providing medical summaries for the Mattes and Ennis case, it's clear by looking at the facts, and we put this in our brief, that there was little to no information exchanged between the parties. He was provided with medical records and then wrote his summary for Mattes. That case settled before any expert disclosures happened.

And then for the Ennis case, Dr. Kinney only billed one hour of time for it and it settled before there was a case management conference.

It is clear there would be no need at this point in time for Bard to provide Dr. Kinney with any of their work product, any mental impressions, any strengths and weaknesses of their case. These cases weren't even developed to get to that stage in the litigation.

So as I said, Bard has had many opportunities to provide supportive evidence for this motion. Documents -- they could provide their billing records to show us the time they've worked with Dr. Kinney, request an in-camera review, at his deposition they could have elicited testimony. Submit a sworn affidavit or declaration from any of the attorneys

that worked on Ennis or Mattes, from any attorneys in the MDL, or from any Bard employees.

So, once again, Bard has not -- has no authority right here. None of the cases that plaintiff or defendant cite is analogous to the position here. They all require some sort of evidence. And in the absence of evidence, a sworn declaration is sufficient.

One thing I noted when I was reading the cases is that the longest period of time between when an expert worked as a consultant and worked for another party was about four years. Right now we're dealing with a time period of 10 to 12 years.

This is greatly prejudicial to the plaintiffs. Disqualifying Dr. Kinney would be fundamentally unfair and serve as a severe sanction there currently is no time to repair.

And Dr. Kinney offers a very unique value as an expert with Dr. Kalva and Dr. Roberts. He is highly specialized in his field. Besides having a medical degree, he is a mechanical engineer and he has a degree in physics. He's designed medical devices. And he is -- was our lead attorney in this project. He was responsible for involving Dr. Roberts and Dr. Kalva.

Dr. Roberts is his supervisor and boss and Dr. Kalva he's known for years, 13 years, and they worked in the angio

clinic in San Diego. And because of their experiences with Bard filters and their complications, that is why he reached out to them and got them involved in this.

So, in summary, Bard has not met their burden, they have not produced any evidence, it's very prejudicial to plaintiffs. Dr. Kinney has signed a sworn declaration and testified under oath. The Mattes and Ennis cases only involved medical summaries.

For the expert report, the Kinney-Kalva-Roberts report does not reflect or reveal any confidential information, nor as Bard asserted that, nor does it reveal Bard's mental impressions, and it does not discuss any of the topics that Dr. Kinney consulted on.

Dr. Kinney has been transparent from the very beginning by outlining his role as a Bard -- his role working with Bard and his involvement. And any indication that confidentiality still exists has either been extinguished by time or by publication.

So we believe it is clear Dr. Kinney should not be disqualified because Bard has not met their burden and Dr. Kinney did not receive any confidential information that is relevant to this lawsuit that was not subject to discovery in this case. Thank you.

THE COURT: All right. Thank you.

MS. HELM: Your Honor, may I briefly address --

THE COURT: Yes.

MS. HELM: I'm going to start with, Your Honor, Dr. Kinney and plaintiffs continue to argue there's no evidence that the expert used confidential information he received.

THE COURT: I think the argument was there is no evidence he received confidential information.

MS. HELM: I'll address that first, Your Honor.

The evidence is in the form of the declaration of Dr. Kinney. In his declaration he testifies that he worked as a consultant for Bard relating to IVC filters, that he performed an animal study evaluating filters, that he was asked to evaluate various performance characteristics of IVC filters, that he was asked to provided advice and consultation regarding the use of filters to other people, that he, again, was asked to perform another animal study and, in fact, the consulting agreement that he refers to there includes the test protocol, which is clearly confidential information. He was asked to provide research related to another animal study and asked to evaluate various performance characteristics of a filter, another IVC filter.

He admits he had access to test protocol, he had access to analysis of Bard's product. He admits he met with the president of Bard Peripheral Vascular and talked about adverse events. Dr. Kinney himself admits in his declaration

that he had access to and received confidential information from Bard while working as a consultant.

He also admits that he received work product while working as a medicolegal expert for Bard because he admits that he reviewed documents provided to him by defense counsel.

Documents chosen by defense counsel to give to an expert are work product. That fact alone shows that he received work product information in his capacity as a medicolegal expert for Bard.

All of this is in Dr. Kinney's declaration: "I met with John McDermott, the president of BPV. We talked about issues related to IVC filter fractures."

Those are the very issues in this case.

He asked questions about whether fragment filters could cause additional issues. Those are very issues in this case, can fracture lead to something else.

He was involved in confidential internal information, internal conversations, in the company about the company's filters and its performance of its filters. He had access to test protocol. He had access to company documents.

So, again, the test is not did he use it. They admit he had a confidential relationship. The test is, in that confidential relation did he receive confidential information? And he also admits that in his declaration.

Interestingly, Ms. Smith argued Dr. Kinney has been

transparent. Apparently he wasn't transparent until he got caught because he either didn't tell plaintiffs' counsel or they didn't ask him if he had previously worked for Bard or for Nelson Mullins as a medicolegal expert, and in fact he had. And then once we raised the issue, once we learned about it and raised the issue, he remembered it.

Now I'm going to switch to Dr. Resnick because the issue is a little different. Again the test is the same. As to Dr. Resnick himself, did he have access -- did he have a confidential relationship? There's no question he did. He admits to it.

Did he receive confidential information? Again, the very simple, very easy one is Mr. Rogers chose what medical records to send to him to review. That is work product in and of itself.

In the analysis of the Austin case, which, by the way, Your Honor, is still pending and many of the lawyers in the room are attorneys of record in the Austin case. The Austin case is the case which Mr -- Dr. Resnick met with Mr. Rogers.

We did not know Dr. Resnick's full involvement and how intertwined he was in the SBBK reports until the depositions of Dr. Desai and Dr. Vogelzang and until we received the invoices, and it was at those depositions that we received the invoices. And the invoices are exhibits to our

motion.

Those invoices --

THE COURT: I've read them.

MS. HELM: And it was at that deposition of Dr. Vogelzang that Dr. Vogelzang testified over and over and over again that his reports, their reports, are a collaborative effort that all four of them were involved in and you can't parse out who wrote what. And looking at the invoices, clearly Dr. Resnick had his hand in every aspect of their expert work.

Dr. Resnick, according to Mr. Rotman, didn't remember that he'd served as a consultant at Bard and didn't remember that in 2015 he'd met for three hours with Mr. Rogers. Again, that begs the question why wasn't he asked? And also, when asked to write a declaration, Dr. Resnick suddenly remembered all of the details of those meetings and his consulting agreements.

But, again, if you look at his declaration, he says, "I met with Mr. Rogers. We discussed the Austin case. Mr. Rogers -- we talked about causation, we discussed the case."

The Austin case is a G2 Express or G2X case, like many of the cases in the MDL.

He also testified that when he worked for Bard he did a product line review. He had discussions with Bard about

filters. He did an animal study. He participated in a preexisting animal study on two separate occasions.

Again, to participate in the study he had to have access to test protocol, test requirements, test results, all of that is conf- --

THE COURT: Let me interrupt you for a minute.

Even if we assume he had all of that information, and even if we know that he collaborated on the report, don't we have to make an assumption that he shared the confidential information with the others?

MS. HELM: No, Your Honor, because they're an entity --

THE COURT: What's the proof he shared it?

MS. HELM: We don't have to prove that he shared it. We have to prove they had access to it.

THE COURT: Well --

MS. HELM: Under both tests the standard is confidential information and -- I'm sorry. Confidential relationship and did you receive confidential information.

THE COURT: Well, did you receive. My point is what is the proof that Vogelzang and Desai received confidential information, other than the assumption that they learned it during this collaborative effort?

MS. HELM: I think -- Your Honor, I think you have to make an assumption if you treat Vogelzang and Desai as

separate from Dr. Resnick but --

THE COURT: I want to talk about the entity issue in a minute. I just want to focus on that first.

MS. HELM: Okay.

You are correct that we don't have evidence showing that Dr. Resnick shared confidential information directly with Vogelzang and Desai. What we have is that his hand was in everything and that they -- I mean, other than one phone call, if you look at the billing records, other than one phone call there is nothing that Vogelzang or Desai did on the their own.

THE COURT: Right. I understand that. But there's still an assumption that that led to the sharing of information, if I'm looking at Vogelzang and Desai individually.

MS. HELM: Yes, Your Honor.

THE COURT: The Ninth Circuit handed down a decision on this issue last week. It's an unpublished decision, but it adopts the *Hewlett Packard* test --

MS. HELM: Yes, Your Honor.

THE COURT: -- and says the information that confidential information was shared has to be proven with specific and unambiguous evidence.

And it seems to me if I focus on them as individuals, there is no specific and unambiguous evidence that they ever received Bard confidential information. Do you agree with

that?

MS. HELM: Your Honor, I think I have to agree with that.

THE COURT: On the entity issue, which I wanted to talk to you about and where you were going a minute ago, I read, I think, the three entity cases that you cited. They absolutely talk about an entity being disqualified, but I didn't see in any one of them an analysis or discussion of why that works or whether everybody in the entity is disqualified and, if so, how that's consistent with this requirement that the drastic remedy requires specific and unambiguous evidence.

My question is, are you aware of a case that's wrestled with the question of how the entity doctrine applies in this setting, and why it is that it would be fair to say that everybody in the entity is disqualified?

MS. HELM: Your Honor, the first part is other than the cases we cited, I'm not aware of any other case.

The second part of your question is why does it make sense to disqualify the entity for the acts of one doctor. And I think in the facts of this case it doesn't make sense to do any other. To reach any other result. And I think, again, Dr. Vogelzang tells you that. And in his deposition, and it's page 28 and page 40, he says over and over again this was a collaborative effort. And you have a situation here where if you let Dr. Vogelzang and Dr. Desai testify, the entity is

going to benefit from that.

Dr. Resnick, who everyone admits shouldn't have been involved and apparently is no longer involved, is a one-fourth owner in the entity. The entity is who's billing, the entity is who's set up to do the consulting work in this case. So you have a situation where you're going to let two people testify but the entity benefit.

And I think in this situation, based on Dr. Vogelzang's testimony "we did this together," based on the evidence that is before the Court that it's clear "we did this together," that you can't benefit part of the entity and you have to treat them as a whole. They acted as a whole. They collaborated. They billed as whole. They all worked on it together. And so the entity itself has to be disqualified. Thank you.

THE COURT: Okay. Thanks.

Let's talk about the motions to exclude Parisian and Kessler.

MR. ROTMAN: There is nothing further we can add on to the entity issue.

THE COURT: I don't think you need to. I think I understand your position and what your arguments are on that.

I will tell you that what I don't need to hear argument on are the number of cases that have disqualified Dr. Parisian and why; we've read them all. Or the number of

cases where she's been permitted; we've looked at those, too.

I don't need to hear argument about whether or not narrative testimony is permissible or about whether experts can venture outside of their area of expertise. None of that is controversial.

It seems to me with respect to Parisian there are those general arguments and there's -- it's virtually impossible for me to do line drawing now and say what would or would not be a permissible description of the facts in an answer or to try to enumerate all of the places in her testimony or Kessler's testimony where they might be stepping outside of the bounds of their expertise. There's just too many of them in the 547 pages of expert reports that the two of them produced.

So what I'm going to end up doing on those issues is some general statements. I'll say that an expert can give an opinion and can explain the factual, the medical, the technical basis for the opinion. Where that kind of an explanation crosses the line between properly supporting an opinion and venturing into a narrative about the facts or gratuitous argument about the facts can only be determined at trial in the middle of a question. I'm not going to let experts wander all over the map. I'm not going to let them give gratuitous narratives or comment on evidence or argue evidence to the jury. But they've got to be able to support

their opinions and explain to the jury why their opinions are justified.

So it seems to me, given the fact that I'm going to provide that general guidance and we're just going to have to draw those lines at trial, with respect to Parisian there's an argument defendants have made that she doesn't identify her methodology. I've read her methodology description in her report. I've read it in her deposition. I understand the argument. That may be a point that folks want to address further.

There is this argument with respect to both Parisian and Kessler about what is or is not a legal conclusion. I might as well share with you some thoughts now so you can address them -- you can come to the lectern -- when you make the argument.

On the legal conclusion issue, there is some unhelpful and unilluminating case law out there, including a very recent case from the Ninth Circuit.

I'll tell you my view of legal conclusions. If you're going to have an FDA expert on the stand and the FDA expert is going to be describing how the FDA works, how the 510(k) process works, whether or not Bard complied with it, and I want to talk in a minute in response to questions about whether that's relevant, but if an expert's going to do that, the expert's going to be talking about legal issues. All of

those procedures are set by regulations. You can't talk about procedures without talking about the law, the regulations, that creates them.

And so it's going to be impossible for us to try this case in a way, I think, unless we get the FDA out of it entirely, which I don't think is going to work, without having experts on the stand who are discussing concepts and standards and procedures that are set by law, and are in the regulations, and probably are opining on whether Bard did or did not comply with certain of those.

Those are not improper legal opinions, in my view. That's an expert in a regulated area giving opinions on a regulated area.

Obviously the expert can't instruct the jury on the standards that apply, but those will be state law standards. In the Booker case they'll be the Georgia law standards for the two claims that remain: Design defect and failure to warn.

I think it is impermissible for an expert to give an ultimate opinion on a question of law that answers a liability question for the jury. But the Ninth Circuit has just held that an expert can use the very language that's in the jury instructions in an element of a claim in describing their opinion and why it's met. That's not inappropriate.

And I say all of that so you can help me understand

this area, but I'll tell you, I think that's another area where we've just got to make calls at trial. We can't say none of it can happen, we can't say all of it can happen, we're just going to have to make judgments as we go forward.

So with that monologue, let's hear your argument.

MR. ROGERS: Thank you, Your Honor. Jim Rogers on behalf of C.R. Bard here to address Dr. Parisian and Dr. Kessler. And I'm assuming Your Honor would like for us to do that all together; there's no reason to parse out those two individual motions?

THE COURT: I agree with you. I agree. And I do have some real specific questions for both sides about their opinions, about strategies in the case that will inform my decision, but I want to make sure you first get to cover the points you think are most important.

MR. ROGERS: Thank you, Your Honor. And it's very helpful to have your framework of how you're viewing this moving into the argument. And I will take you up a little bit to talk about the methodology for Dr. Parisian since you kind of invited me to do so.

And, Your Honor, I'm sure you've probably seen in both the case law and in Dr. Parisian's report where there are these narrative portions of her -- both the report and then the testimony that she gives which are long recitations of various bits and pieces of documents and then kind of

concludes all of this in a very sort of Grisham-like fashion to sort of weave a story of corporate malfeasance.

And, Your Honor, the things that sort of need to be there as the glue to hold those opinions together just are absent. And Your Honor has probably noticed that in her report she will often start with these general opinions and sort of give a brief summary of what they are, and then below each of those there's just sort of a string cite of federal statutes from the FTCA and also from FDA regulations, and there's really nothing that connects those things. And that's really the problem with the methodology, that it's really not there --

THE COURT: Let me interrupt you and have you address something specific.

I agree that's an accurate description. And somebody ought to help Dr. Parisian learn how to write an expert report. I mean, the problem she has in this report is exactly the problem judges have stumbled over again and again where she'll announce an opinion, she'll have a one-paragraph description that says nothing about legal standards, she'll have a string cite of regulations and then 50 pages of factual discussion. It is very hard to figure out where she's coming from.

However, if you read the 30 some odd pages at the beginning of her opinion where she talks about the FDA process

as well as her qualifications where she says where she worked in that process and she says in that description that what these different divisions that review 510(k) proposals do is review various categories of information, if you put that in your mind and then you start reading her opinion and her factual discussion, it makes more sense as to how she is coming up with her opinion. I think she's saying I'm doing here what the FDA taught me to do in the 510(k) process and here are all of the problems I see.

So the question is can I -- why can't I look to that description of FDA procedures, her role in it, and then look at her opinion, factual basis, and see if they mesh to close the analytical gap?

MR. ROGERS: Your Honor, I would certainly agree with you, and we're certainly familiar with your opinion in the *Placencia* case *versus I-Flow* where Dr. Parisian nor Dr. Kessler was at issue but Peggy Pence was, who is a similar type regulatory expert. And Your Honor held that there was certainly things about the FDA regulatory process that are beyond the ken of your average juror, that it would be helpful for them to hear about that process. And I think that that is correct, that it would be perfectly okay for regulatory experts to talk about how these products come to market, what they look at, what FDA evaluates.

But the disconnect that I see with what you're

talking about as setting up that as the framework and sort of filtering the rest of the report through that framework is that Dr. Parisian, the vast majority of what she addresses in her report are not things that the FDA typically ever sees and probably doesn't want.

I mean, she does not talk about FDA regulatory filings. Instead, Your Honor, it is a litany of internal documents, e-mails, PowerPoints, deposition testimony, things of that nature, that are not ever part of an FDA regulatory record and that are not things that FDA would ever -- would ever cross anybody's desk at the FDA. And so it is sort of an after the fact thematic presentation of the plaintiffs' theories and themes in the litigation and how it all ties up. And, really, Your Honor, what is, in effect, essentially it's doing a attorney argument or closing argument in the middle of trial.

THE COURT: Well, let me -- let me ask you a question based on that. Absolutely an expert can't give a lawyer's closing argument at trial, and if you read just some of those narrative portions, it looks like that's what she's doing.

I have assumed, and I want to know if this assumption is correct, that what Bard wants to do at trial, part of what Bard wants to do, is help the jury understand that the device in issue went through the FDA 510 clearance process, was cleared by the FDA, the warning that was given was cleared by

the FDA, and that what Bard wants to assert to the jury through that information is we did exactly what we're supposed to do and a federal agency confirmed that we'd done what we're supposed to do.

I'm assuming Bard wants to say that to the jury.

If that assumption is correct, it seems to me it's entirely appropriate for the plaintiffs to then say to the jury, no, they didn't do exactly what they're supposed to do with the FDA, and here's why. Here's the information they should have told the FDA that they didn't tell the FDA. Here's what should have been a warning on these issues that they never raised with the FDA.

If Bard is going to use the FDA as part of its defense, isn't it appropriate for the plaintiffs to say they didn't comply with what the FDA requires?

MR. ROGERS: Your Honor, I think they go much, much further than that, and that kind of also dovetails into what you said earlier about legal opinions. And it's not just here's this piece of information that I think FDA would have liked to have known that FDA was not provided. I mean it moves into these legal determinations as to the violation of regulations, the determination that products were adulterated and misbranded and, Your Honor, I believe that moves into the province of the fact finder and not the expert.

I mean those are legal determinations that should be

left up to the jury to determine if there is some sort of violation or some sort of determination that a product should be adulterated or misbranded.

THE COURT: Will you have an expert at trial that will say to the jury Bard complied with the FDA 510(k) process?

MR. ROGERS: We certainly have experts that walk through the process and describe what the regulatory filings were, how the process worked, and what the ultimate determination was by the FDA.

THE COURT: And will they give opinions that Bard complied with what the FDA required?

MR. ROGERS: Your Honor, there are probably things like that that are in their reports right now, but, you know, that's also -- they were prepared also in response to the reports of Dr. Parisian and Dr. Kessler. Obviously those types of issues, our folks have to respond to.

But I don't think that it is necessarily appropriate for anybody to really determine for the jury if there was compliance or not compliance.

THE COURT: Well, let me try give you a hypothetical.

Let's assume that the Bard expert testifies, perhaps without stating an express opinion on compliance, that this is what the 510(k) process is, these various steps, this is what Bard did at each of those steps. The result was the FDA

cleared this product. The clear implication to the jury being Bard complied with the FDA 510(k) process.

And let's say the plaintiffs then want to put an expert on the stand to say at the time Bard engaged in this step that the defense expert described, it knew a lot of information about failure rates and harmed patients that it did not disclose to the FDA, and under FDA requirements or regulations it was required to disclose that information.

Is that objectionable for them to do those two things?

MR. ROGERS: I certainly think the latter part is, Your Honor. If you're talking about perhaps things that here is a part of information that I as a regulatory expert believe that the FDA would have liked to have known, I think that that is much more on the side of acceptable methodology as far as a legal opinion is concerned versus compliance or noncompliance with the regulation.

THE COURT: Let's assume the expert says that but then says Bard was required to disclose these additional failure rates under the regulation which reads as follows, which is part of the 510(k) process.

Objection from the defense.

What's the basis upon which I sustain the objection?

MR. ROGERS: That the -- the evidence that the jury's about to hear states a legal conclusion and that that violates

the province of the fact finder as well as to whether or not there was a violation.

THE COURT: Are you suggesting that at trial I'm going to be instructing the jury on all of the regulations that apply in the 510(k) process, and I'm going to be telling the jury you have to decide whether or not Bard complied with the 52 pages of regulations that make up the 510(k) process?

MR. ROGERS: Your Honor, I agree with you that that would be unwieldy. But recently, and I don't know if Your Honor followed it but there was a another trial involving a different defendant in Indiana --

THE COURT: I didn't follow it.

MR. ROGERS: -- in the Cook IVC filter MDL. And, Your Honor, in that case, as I understand it, Dr. Kessler testified and he was allowed to talk about the regulatory standards.

In other words, he was allowed to put up for the jury here is the statute that says what "adulteration" is under the regulatory scheme and here's the statute that says what "misbranded" is under the regulatory scheme, but he was not allowed to tell the jury in a conclusory opinion fashion that this statute was violated by Cook and hence the products were adulterated or misbranded.

THE COURT: Well, okay. Going back to my hypothetical, would it be all right, then, for a plaintiffs

expert to say FDA regulations requires a 510(k) applicant to provide the following three categories of information, and here is information in those three categories that Bard had, describe all three categories, that was not disclosed. Is that okay? Never states at the end it's my opinion the regulation's violated.

MR. ROGERS: Understand, Your Honor. I think that falls into the much more acceptable category as opposed to saying this was a violation of a regulatory standard.

THE COURT: The quid pro quo for that would have to be no Bard expert can say Bard did comply with the 510(k) process. Do you agree?

MR. ROGERS: Absolutely, Your Honor. I think we're going to have to recognize the well-known and loved goose-gander rule, that I don't think that either party is going to be able to do something that the other party's not going to be allowed to do.

THE COURT: Well, obviously I'll hear from the plaintiffs in a minute, but assuming that's where we draw the line at trial, that experts can describe the legal standard and describe the facts in each of those categories and let the jury draw the conclusion as to whether the standard was or was not violated, there certainly would seem to me to be ample materials on that very approach in both the Kessler and Parisian reports so that if they were to follow that approach,

they're not lacking on information with which to do that.

MR. ROGERS: Your Honor, I would have to agree with you in that regard.

THE COURT: So isn't this really, then, a matter of our deciding how FDA experts should testify on each side?

MR. ROGERS: I think you're right.

THE COURT: Let me ask you one other question. And this is going to be a question for the plaintiffs as much as for you.

As I'm sure you know from that *Placencia* decision that I issued, Arizona law, when it's addressing the standard of care in a case, allows a jury to hear about federal law requirements, federal regulations, to help establish the standard of care.

I don't know what Georgia law says on that subject. But if Georgia law, like Arizona law, says a jury can consider federal legal standards in deciding what the standard of care is, then do you agree that experts on each side should be able to testify about what the federal legal standards or requirements are under the FDA?

MR. ROGERS: Your Honor, I don't know the answer in Georgia, either. I think you're certainly correct that -- you know, as far as today is concerned, I think we're kind of talking about these issues sort of globally, but when it gets down to the case-by-case determination, obviously there's

going to be individual differences in state law that will determine some of these issues that we'll have to address via motions in limine or other lawyer argument down the road.

But to address your question, if there is a specific state law that says that federal standards can be considered, I think that obviously the jury's going to be allowed to hear something about the federal standards. And then it depends on what that is that the jury actually gets to hear.

And, Your Honor, I believe in the *Placencia* case, I mean, obviously you were dealing with it from an FDA perspective, but the underlying case law that came from the Ninth Circuit dealt with it from a OSHA perspective, is my understanding of the reading of that case. And, again, there may be some differences. Meaning that I think your opinion relied on a Ninth Circuit opinion that dealt with the admissibility of some OSHA standards.

THE COURT: I can't remember. I don't doubt you're right. What I do remember --

MR. ROGERS: I wouldn't bet on it, Your Honor, my memory's not that good.

THE COURT: What I do remember, though, and I think this is important for this case going forward, is specifically to be looking at Arizona law and asking, since it was Arizona law governing the claim, are federal legal standards relevant in this state that that was a negligence claim, and the

Arizona case law said yes, they are, that goes to the standard of care.

If Arizona law had said no, then I don't think any of that FDA stuff could go to the standard of care. Now, it might still go to the defense issue we were talking about a minute ago.

And, yeah, I don't remember the Ninth Circuit law I was looking at.

Did you have other points you wanted to make? And I'm happy to hear your thoughts as well after I hear from plaintiffs on this issue.

MR. ROGERS: Your Honor, the only thing I will do that might be helpful for the Court, I think Your Honor's clearly got the legal issues perhaps not completely sorted out in your own mind but I think you have really read what you needed to read and I think you have arrived at sort of a construct of the way you think this ought to look. And, Your Honor, what I will hand up, if it's okay, is a couple of charts that we had prepared that really just sort of bucket by bucket of the various legal arguments that we made by expert that really identifies, using their reports, the specific portions of their report that we believe fall into each of those buckets.

THE COURT: That's fine.

Mr. Rogers, did you have other points you wanted to

make besides those?

MR. ROGERS: Your Honor, I really don't. I think Your Honor obviously realizes we're not plowing any new ground here. There's a lot of cases that you can find regarding both of these experts that go each way and it's really a question of trying to dial it in appropriately for this case, and I think Your Honor's done that.

THE COURT: Okay. Thank you.

MR. ROGERS: Thank you.

MR. ARBITBLIT: Good afternoon, Your Honor. May it please the Court. Don Arbitblit for plaintiffs.

I think I will not use the PowerPoint I had prepared because most of it Your Honor covered in your preliminary remarks. I would like to respond to some of the colloquy that just took place. I'll start with the last point, which was Mr. Rogers' assertion that you could find cases going both ways on both of these experts.

I'm not aware of any case that's ever said Dr. Kessler's excluded. There have been cases in the past that have excluded Dr. Parisian entirely, and Your Honor has stated what the issues have been and some of the concerns that you have.

However, in my research on Dr. Kessler, which I tried to be as thorough as possible, I have seen occasional opinions, such as Judge Goodwin in West Virginia and a recent

Indiana case, that have guided what he can and can't testify to, in particular as to the issue you raised concerning what is and is not a legal conclusion, as to which I agree there are cases that are not particularly helpful. But there's no case out there I'm aware of where anyone has said Dr. Kessler can't testify, and I think that is important for the Court to understand. Thank you.

On the particular issue of what is or is not a legal conclusion, I do think that the *Placencia* case is relevant and not only *Placencia* itself but the case Your Honor relied upon, which is the *Wendland* case. That's one of two that were cited for the proposition --

THE COURT: What's the court for that one? Is that Ninth Circuit or is that an Arizona --

MR. ARBITBLIT: That is the Arizona case involving failure to put up OSHA standard protection around the --

THE COURT: That's the one that said federal law can inform the standard of care?

MR. ARBITBLIT: Yes, but it went beyond that, Your Honor. And specifically, the important part that went beyond for our purposes today goes to another point that was discussed a few minutes ago, and that was how far can the expert go in testifying. And what the court allowed in the *Wendland* case was specifically that the expert testified that the defendant, quote, did not comply with OSHA standards, end

quote. That was permitted.

And I agree with Mr. Rogers' characterization of what happened in the Indiana Cook filter case, which is that the judge allowed Dr. Kessler to put up the regulations, say what they meant as far as adulteration, meaning it's not what it purports to be, misbranding, meaning it was misleading in some particular relevance to the doctors and patients and to the FDA, and to describe the conduct, but he wasn't allow to make the connection and say I believe that this product was misbranded or this product was adulterated or this product was not substantially equivalent, which would be the counterpart aspect for the 510(k) process of regulations.

I think that was a mistake in ruling. I think that if you look at other cases, such as the *Phillips* case, which is a specific case involving Bard and Judge Jones in Nevada, Judge Jones specifically said, and this is with Dr. Parisian as the expert, "This Court" -- "The Court disagrees that Dr. Parisian's conclusions that defendants violated this or that regulation amount to legal conclusions on ultimate issues. Defendants are not charged in the present case with violations of any regulations. Their alleged violations of regulations are merely relevant to whether they satisfied the standard of care, and" --

THE COURT: Let me interrupt you for just a minute. I've read Judge Jones' decision, and I know him and I have a

high regard for him.

MR. ARBITBLIT: Yes.

THE COURT: But it seems to me this is an area where when you're doing legal research you're just searching for friends. You can find a case that will support almost any position when it comes to what is or is not a legal conclusion.

What's the guiding principle?

MR. ARBITBLIT: Fair enough, Your Honor. I've been trying to wrestle with that question myself. I've even read a couple law review articles on the subject. One was from Cleveland State law review. Basically the author's position was that Rule 704 had not gone far enough in clarifying that the ultimate issues that are not inappropriate for testimony should include legal conclusion so long as the expert is aware what the Court will instruct and issues opinions that are in conformity, in congruence with the Court's instructions. As long as -- if the expert's qualified and the opinion is helpful to the jury, those would be the standards this particular reviewer -- definitely would be a friend to the plaintiffs, Your Honor, since we're looking for friends.

But the standard I think has been applied by several courts that I think can draw the line is that the legal conclusions have to do with the state law that applies to the plaintiffs' claims.

In other words, in the Actos litigation where Dr. Kessler testified to the violation of 201.57, had the duty to warn, the court said that's not a legal conclusion because the legal conclusion is whether the product was defective under New York state tort law or whether the defendant was negligent under New York state tort law.

I believe Judge Jones was saying pretty much the same thing in the Nevada District Court case, and in particular said that Dr. Parisian was permitted to testify to the FDA regulations and whether defendants violated them.

That's also the case in the *Tillman v Bard* case in the Middle District of Florida where the expert was permitted to testify to his opinion as to whether Bard complied with all regulatory requirements applicable to the G2 filter.

So the line that I've seen drawn that I think is helpful, to the extent there can be some clarity, is that the legal conclusions have to do with how the court instructs the jury on the elements of a state law tort claim.

THE COURT: I assume you agree that if a judge allowed those kinds of opinions that -- well, you'd agree on two things, I think. One, it's got to be reciprocal. Both sides can have that opinion given. So Bard can have their experts say Bard did comply.

MR. ARBITBLIT: Yes, Your Honor.

THE COURT: But, secondly, it seems I would need to

instruct the jury that whether or not Bard did or did not comply with an FDA regulation, or an expert's opinion on that, should not control your verdict in this case; you may consider it only in deciding whether or not Bard failed to warn within the meaning of the Georgia state law explanation. Or designed defectively within the meaning.

I mean, there would have to be a careful limiting instruction on that. Don't you agree?

MR. ARBITBLIT: I do agree, Your Honor, and I think that that is consistent with the *Wendland* case that Your Honor referred to in *Placencia* to the extent that the court there said that the violation of the OSHA regulation as to which the expert said you can testify that the defendant did not comply, that was only evidence toward the legal standard and that the defendant was permitted to put on its own case as to why that was not a sufficient basis or the only evidence that the jury could consider.

So, yes, I do think that that is an appropriate limiting instruction as Your Honor has stated.

THE COURT: Well, let me ask this question to both sides: It seems on this issue, and this is painting with a broad brush, but we could either say experts can do what was allowed in the Cook case, they can lay out the standard, they can lay out the parallel facts, and let the jury line them up, or they can add to that, "and I think it did comply" or "I

think it didn't comply," but then I instruct the jury very carefully what to do with that opinion.

As between those alternatives, is that something on which the parties could reach agreement as to which of those approaches makes the most sense?

MR. ARBITBLIT: I would be very doubtful about it, Your Honor. My guess is the plaintiffs would argue strongly for having the experts be able to say that there was a violation of applicable regulations. And I think it goes --

THE COURT: You say they would argue to it?

MR. ARBITBLIT: The plaintiffs' experts would argue for the position they be permitted. The plaintiffs' lawyers would argue for the position --

THE COURT: I know what you're arguing for. I understand.

MR. ARBITBLIT: The experts should be permitted to say the regulations were violated because --

THE COURT: With a limiting instruction.

MR. ARBITBLIT: With a limiting instruction, but specifically because of the laws saying -- the precedent saying that compliance is part of that overall presentation and because of the complexity of the entire area, which, as Your Honor pointed out in the *Placencia* case, and many other as well have, this is a very complicated area.

So to ask the jury to take the facts -- they've got

an 800 paragraph, 800-pound gorilla, of a declaration they submitted to Your Honor for the preemption motion. We've got the 540 pages of expert reports. It's not a simple matter to just line up the facts with those regulations.

THE COURT: Time limits are going to help on both of those.

MR. ARBITBLIT: It's on us to make the presentation reasonable. And I did want to mention that I actually looked at the time at one of Dr. Kessler's direct examinations and it was two hours including voir dire.

THE COURT: Let me interrupt you for a minute because Mr. Rogers has been standing to say something.

MR. ROGERS: Your Honor, I stood up because you said you were asking both sides. And as I understand your question, you were asking whether or not the parties could at least potentially agree on a system by which both sides would have an expert who would testify that here's what the standard is, it was either violated or it was not, and that there be a limiting instruction as to what that means.

THE COURT: Right.

MR. ROGERS: Your Honor, I think that's something we can talk about. I wouldn't just out of hand say it's not possible that we would ever agree. But I also think, Your Honor, as we move closer and closer towards trial and there are going to be probably additional rulings about the

regulatory world as it is going to be presented to the jury, I think inevitably the parties are going to have to have discussion about, you know, what the world is going to look like as various issues start to sort out.

THE COURT: I agree with that. It will have to happen.

And I am not going to try to decide on the basis of today's argument which of these two approaches makes sense. I need to know more about the case if I'm going to be making that decision. I'll obviously make it before trial. But I would encourage you to think about that because, well --

MR. ARBITBLIT: If I could make one more point, Your Honor. And it has to do with the argument made by defense counsel having to do with information that would not -- that the FDA would never normally see, and because it's not required under the regulations.

There's -- there are a few specific areas where that should be looked at in a different light, and that has to do with something that happened in the Actos litigation that's in the ruling that we provided to the Court, and that has to do with an analogy -- an analogous internal assessment of adverse events. Analogous to what Bard had done here.

And having done that analysis Takeda, the defendant in that case, found some things it didn't like, in particular that there was a higher reporting rate of bladder cancer,

which was the alleged injury associated with that drug.

When they submitted to the FDA six months later a summary of information about bladder cancer, they had done a revised analysis that left out some of the important facts. And so the FDA never knew that Takeda had analyzed the information in a different way and found a statistically significant increased reporting rate for bladder cancer. So that -- and their defense was, we didn't have to do it so there's no reason why there should be a problem and Dr. Kessler should not be allowed to testify to it.

The court disagreed and said that regardless of whether they had to do it, they did it, and having done it, they should have provided it. And Dr. Kessler was permitted to testify to that effect.

And same thing holds true with a number of things in this case: The statistical analysis of May 2004 showing statistically significantly higher reporting rates of deaths with the Recovery filter; the bench testing at the same time that showed weaker migration resistence; and the internal worrying about the fact you had those two contemporaneous signals of a problem at the same time, the weaker migration on bench testing supporting and mutually reinforcing the higher reports of death, the bench testing in the G2 case showing failure on the caudal migration in 2006.

Those are not required and they weren't required to

produce them. But having done them, it's hard to think that the FDA wouldn't have wanted to know or doctors and patients wouldn't have wanted to have known about those results.

THE COURT: Okay.

MR. ARBITBLIT: Thank you.

THE COURT: Let me ask you a couple of other questions.

MR. ARBITBLIT: Yes, Your Honor.

THE COURT: I have long had a rule in trials that I don't allow more than one expert on a subject. There is a lot of overlap between the Kessler and Parisian reports and between some of the other reports I've seen so far.

I guess the question is, was that done out of abundance of caution? Or does either side think you should be allowed in a trial to have two experts get on the stand and express the same opinion?

MR. ARBITBLIT: Certainly with the regulatory experts I cannot imagine a situation in which both Dr. Kessler and Dr. Parisian would be asked to testify. I think the situation with MDL's is multiple experts are useful for multiple trials and you can't count on one to be present on all occasions.

I wouldn't want to speak too much on the other experts that are not my bailiwick because they may have other areas of expertise to address the same subject. For example, a radiologist or some other expertise might be talking about

the same thing from a slightly different perspective. And others my address that more properly than I.

THE COURT: Do defendants have a disagreement -- any disagreement on --

MR. ROGERS: No, Your Honor. We agree. I don't think we envision a scenario where you'll have two regulatory experts testifying at one trial.

THE COURT: Let me -- let me ask a couple specific questions about Kessler that I was thinking about in trying to start formulating my views on where lines should be drawn in all of this. I'll pick examples. There are a number of these.

But, for example, there are several different places in his report where Dr. Kessler states the opinion that the Recovery filter and the G2 filter should not or could not have been legally marketed. Why is that relevant in a case of failure to worn and design defect?

MR. ARBITBLIT: Well, it's relevant to at least punitive damages because the conduct in keeping it on the market for profit would be relevant at least to that extent. Obviously, if it weren't on the market there wouldn't be any reason to warn because no one could use it. I don't know if that's the point Your Honor was trying to make with that question.

THE COURT: Well, setting aside punitive damages, and

it's apparent to me there's much in here that may be argued to go to punitive damages, whether or not a filter could or should have been on the market, how does that help the jury decide whether there was a failure to warn to cause the injury or whether there was a design defect that caused the injury?

MR. ARBITBLIT: Well, I think it goes back to the argument about relevance of the regulation and its violation to the standard of care.

In the case of legally marketed, the reason it can't be legally marketed is because it's adulterated and that is the consequence of adulteration. Adulteration itself means the item is not what it's purported to be or represented to be. So that the violation of that regulation is part and parcel of the relevance to the standard of care that --

THE COURT: How? The standard of care, I assume, will be on the failure to warn claim, Georgia law, which says, if I remember it correctly from a Booker motion, I think it says that if there's a significant increase in the risk, then the manufacturer has a duty to make an adequate disclosure. Something like that.

How does the fact that the product could or could not have been on the market say anything about that standard of care?

MR. ARBITBLIT: Well, I do think that the violation of the regulation in itself is relevant to the standard of

care. I can see I haven't convinced you of that position. But I would also add to that that in the case of the G2, the fact -- and I imagine Your Honor's familiar with this position either from these motions or previous motions, that the plaintiffs' position is that if the Recovery could no longer be legally marketed, then the G2 had no predicate to which it could be called substantially equivalent and shouldn't have been on the market either. So there's a larger issue in the case, especially since, as I understand it, G2 is in the bellwether cases as well as the plaintiff population as a whole.

THE COURT: All right. This will be a discussion that will continue. I'm not going to come to any final conclusion, I'm just trying to understand positions.

I mean, it seems to me an opinion that it couldn't be legally marketed, whether expressed in that term, may be relevant to a defense that Bard is making that this was all FDA cleared. But I'm having trouble seeing how a number of these things go to at least the claims in the Booker case.

Let me give you a second example. I'm reading -- actually, I'm reading from your summary of his opinions, but they're consistent with what I saw in his opinions. And I don't know that you need to look at it, but what it says at the bottom of page 4 of your brief is Dr. Kessler will give the opinion that Bard had an obligation to share the testing

information with patients and physicians. And throughout his report, Dr. Kessler says similar things, Bard had an obligation.

When I hear that my question is, an obligation under what law? Is he saying he had an obligation because reasonable interventional radiologists would want to know it? And, if so, is he qualified to give that opinion? Is he saying Bard had a duty to disclose under Georgia law? And isn't that a legal opinion? Is he somehow saying Bard had an obligation under the FDA regulations to tell the physician and patient something?

Can you help me with that?

MR. ARBITBLIT: Okay. There are a number of responses. I'll try not to forget any in my answer.

On the issue of federal regulations, it goes to substantial equivalence and lack thereof. If there are problems with the Recovery vis-a-vis SNF or if there's problems with the G2 vis-a-vis Recovery in the sense G2 had a much higher rate of caudal migration than Recovery did, it raises new questions of safety and efficacy, which means that it violates the substantial equivalence requirement for clearance of that product.

From the sense of an obligation, as opposed to a duty, he's not going to testify as to a legal duty, but his expertise is not limited to FDA regulatory matters. He serves

on the board of private device and drug companies and advises them on compliance issues and has been permitted to testify on the standard of care generally. Not simply as a matter of regulatory law, but also as a matter of whether there was a failure to warn under a state law standard.

So the -- these go to whether doctors and patients would have wanted to know that there was a higher rate of failure with the Recovery than SNF, whether there was a higher rate of failure with the G2 than SNF or Recovery as far as caudal migration.

THE COURT: So when he says Bard had an obligation to disclose this to doctors, what's the source of the obligation he's talking about?

MR. ARBITBLIT: I think the source is the standard of care for a reasonably prudent manufacturer would be to disclose to doctors and patients information that would be relevant to their prescribing decisions.

THE COURT: So your view is that he is qualified to step out of the FDA box and give opinions about what medical product manufacturers should and should not do as a matter of standard of care?

MR. ARBITBLIT: Yes, Your Honor. He has done that in the past and I believe that as a -- he is a physician. He has testified in his deposition to what he's read about the subject. He is not a radiologist, but there are -- there's an

interesting quote, I think it actually has to do with a defense expert in the *Marina* case that the defense cited. If I may just take a look for that. On the very question of qualifications -- let's see if I can find it. In the *Marina* case, the plaintiffs challenge the qualifications of the defense expert, Dr. Feigal, who is a defense expert in this litigation, and the court said at 169 F.Supp. 3d 396 at 463, Dr. Feigal is opining on the adequacy of the Marina label from a regulatory perspective, a field in which he is qualified, which means he does not need to have equally specialized knowledge in a particular medical field.

I think that even though that was particularly about the regulations, the take-home message from that is that if your expertise is in the federal regulations and standard of care and what doctors would want to know and you look at bunch of information that says this product's not as good as what you could have used, which is the issue in the Booker case, that the doctor would have wanted to know, is there a safer filter, and that's -- that's the kind -- that is what Dr. Kessler's testimony would go to, in addition to regulatory. It would be what does the doctor want to know when the company knows that it has information that the product's not as good.

THE COURT: Okay. We probably could do this all afternoon, but let me ask one more.

MR. ARBITBLIT: I'm not sure I could, but I appreciate the opportunity.

THE COURT: It's got two parts to it. He testifies in a number of places in his report something Bard did was misleading, he uses that word. Misrepresentation/fraud claim is out of this case for Booker.

And he also testifies in a number of places that Bard engaged in off-label marketing.

If Ms. Booker's use was not off label, why is that relevant? Why is any testimony about what is or is not misleading relevant?

MR. ARBITBLIT: So, again, more than one answer. I'll try not to take all afternoon. On the question of whether it's about the Booker case or globally, I use the Booker case as an example, but as defense counsel said, we're sort of here on global issues. If there's no off-label marketing happening in a particular plaintiff's case, whether Booker or someone else, I don't think that he would testify to off-label marketing, but I see Ramon thinking he might disagree.

Again, Your Honor, I don't want to make that representation if lead counsel's going to stand up and say we think it's relevant because it goes to bad behavior. It might. It might well go to bad behavior.

THE COURT: Meaning punitive damages?

MR. ARBITBLIT: Yes.

THE COURT: Bad behavior is not a basis for proving a claim. It may be relevant on punitive damages.

MR. ARBITBLIT: Fair enough.

Now, there was another aspect to your question?

THE COURT: Misleading.

MR. ARBITBLIT: Misleading is misbranding, which is a violation of regulation.

THE COURT: Why is that relevant?

MR. ARBITBLIT: Again, it's relevant globally.

THE COURT: Why is it relevant in Booker where there is no misrepresentation claim remaining?

MR. LOPEZ: Your Honor --

THE COURT: Go ahead, Mr. Lopez.

MR. LOPEZ: There's still exists a negligence claim. I know we've been focusing on failure to warn and design defect --

THE COURT: Those are the only two claims left in Booker; right?

MR. LOPEZ: They didn't challenge our negligence cause of auction, just negligence per se.

THE COURT: Negligent what? Negligent design defect, negligent failure to warn. I think those are the only --

MR. LOPEZ: I think we have a general negligence cause of action.

THE COURT: My order doesn't -- it identifies what's left in the case at the end, and it doesn't mention any sort of general negligence.

MR. LOPEZ: But they didn't challenge general negligence in the their motion for summary judgment. I don't -- I'm going to have to check the record, but I'm fairly certain their master complaint --

THE COURT: Let's assume --

MR. LOPEZ: -- includes general negligence --

THE COURT: Let's assume there is a negligence claim. Negligent what?

MR. LOPEZ: Negligent conduct. That could embrace a whole host of things with respect to what a reasonable manufacturer would do under the same or similar circumstance.

THE COURT: Well, if you're going to have Dr. Kessler as part of a negligence claim, if it exists in the case, opine that what Bard did in a particular instance was misleading, aren't you going to have to prove that misleading statement caused Mrs. Booker's doctor to implant the device? And isn't that exactly why I knocked out the misleading claim in Booker, because you couldn't prove that he relied on anything for purposes of a misrepresentation or misleading claim?

MR. LOPEZ: Well, I think you knocked out the misrepresentation cause of action. There's misleading -- it could be negligent. If something is misleading, then it's --

it's conduct that we believe, under the negligence cause of action, is what a reasonably prudent manufacturer would not do.

For example, if they're going to write a label -- there is a federal regulation that says you're not supposed to be misleading when you --

THE COURT: Let's assume --

MR. LOPEZ: -- in Dr. Kessler's report.

THE COURT: I'm not making my question clear.

Even if we assume for a minute I allowed him to say it was misleading, wouldn't you have to prove for the causation part of negligence that that misleading statement caused Mrs. Booker's doctor to put the filter in her?

MR. LOPEZ: Well, we have to relate it to causation. I think we can. I'm not sure I'm prepared to try that part or argue that part of the case right now --

THE COURT: Again, we don't need to debate this further --

MR. LOPEZ: It goes to the label. It really does relate to what's in the label, whether or not the label was misleading, whether or not the information the doctor had in the label was misleading with respect to the true risks and the effectiveness of the device. That's a negligence cause of action.

THE COURT: Okay. I don't -- I don't want to spend

more time on this. I know we could talk about it at length. I don't know whether there's a negligence claim left. I didn't think there was --

MR. LOPEZ: I know they didn't challenge it.

THE COURT: I guess you can tell from this line of questioning that when we get to trial relevancy is something I believe in. And either side, if you're going to be putting in evidence, I'm going to want to know how it is relevant to a claim you are proving in the case or defense you are asserting, rather than something atmospheric that I'm seeing in these expert reports.

MR. LOPEZ: We understand that completely, Your Honor.

MR. ARBITBLIT: Thank you, Your Honor.

THE COURT: Did I cut you off?

MR. ARBITBLIT: I was going to ask, at the risk of extending my appearance, whether omission has been also ruled out by Your Honor's ruling.

THE COURT: Failure to warn is an omission, in my view. You omitted saying something. In that respect --

MR. ARBITBLIT: That goes back to what Dr. Kessler's report is about on certain things being misleading because they omitted to state important facts in addition to what was stated.

THE COURT: I understand that point.

MR. ARBITBLIT: Thank you, Your Honor.

THE COURT: All right. We've been talking a lot about all these issues. I don't know if the defendants want to say anything on these things.

MR. ROGERS: Your Honor, I get the strong sense you probably heard all you want to hear on those issues.

THE COURT: This has been more for my education in the last 20 minutes.

MR. ROGERS: Right.

MR. COMBS: Your Honor, I wanted to address Dr. Parisian you talked about with Mr. Rogers.

THE COURT: What are you going to say? You're not going to stand up and say we should allow liberal narrative testimony from Dr. Parisian, are you?

MR. COMBS: If you want to hear what I have to say I'm happy to say it.

THE COURT: I thought I understood the point, but go ahead.

MR. COMBS: Couple quick points, Your Honor. Number one, I think the Court's characterization of her report is a little unfair. I know there is a format to it of citing -- giving an opinion, listing some regulations and getting into the narrative, but I went through it and flagged, green flagged, all the other times in the body of the report where she cites a regulation. "Bard was required to," and then

cites a regulation. So I think her methodology in her report is fine. To say this isn't enough gets into the defense writing our reports for us. I think that's going a little too far.

But in the big picture, Your Honor -- I'm sorry. Lincoln Combs for the plaintiffs, if I didn't say that at the beginning. I know we're short of time and trying to do this a little informally.

Dr. Parisian's opinions and her testimony is not a secret in this case. In this litigation. You know she was admitted in *Phillips*, she testified, and it was fine. We're happy to submit the transcript if you want to review it. I think I counted 22 or 25 objections in about 140 pages of testimony. Some of them were sustained, some of them were overruled.

So she comes in and testifies and they're free to make objections. And I know Your Honor generally has a preference going by your past *Daubert* rulings and motion in limine rulings for reviewing it as it comes in in trial. And that was the case in *Placencia* with Dr. Pence, who's a very similar expert to Dr. Parisian.

So I think a lot of this is premature in the big picture. Bard is well positioned. Mr. North cross-examined her and objected at trial and it came in and it was fine. There wasn't just an overwhelming abundance of objections. It

was normal testimony. And certainly we can now, with the benefit of that transcript in Judge Jones' rulings on her testimony as it came in, as well as guidance from the Court, I'm sure we can have her testimony come in properly without being narrative or anything like that regardless what's in her report, which is not a legal brief or evidence.

THE COURT: All right. Thank you.

Let's talk for a minute, and then do a break for the benefit of the court reporter, just about some of those issues I put at the end before we talk about the final motion.

I'd like to talk to you about what we're doing from here on out in terms of expert motions. And here are my thoughts on that: In January we have a hearing. January 19th. My intention would be to hear the motions on Muehrcke, M-U-E-H-R-C-K-E, Hurst, H-U-R-S-T, Eisenberg, Betensky, and McMeeking. M-c-M-E-E-K-I-N-G. Those five motions.

You've already indicated you don't think we need oral argument on Morris, Grassi, the Garcia and Streiff opinion, and on the criminal law standard. And so that would leave only one other motion, which would be the Ritchie motion.

I don't know if we can be ready to hear six motions by January 19th or not. It depends what happens with a trial I've got the two weeks before that.

And then we would just rule on the motions submitted

without oral argument as we can get to them. I suspect we'll get better at it and move more quickly as we get through the *Daubert* motions.

Is there any concern about that schedule, taking up those motions January 19? We'll just have to find a place to do Ritchie when we can. Any thoughts on all of that?

MR. NORTH: No, Your Honor. That sounds fine. And we will go back and take a look at Ritchie one more time and see if that perhaps could be submitted without argument.

THE COURT: Ritchie or one of the other five I just mentioned for January 19.

MR. NORTH: Okay.

THE COURT: Any thoughts from plaintiffs on that?

MR. LOPEZ: Plaintiff will be prepared with whatever the Court ends up having on that day.

THE COURT: Okay.

In terms of timing, when we set these trials, the ones in March and May, I set three weeks, that was your thought about what it would take. I have a small conflict the first week in March. We're set to begin on March 13th and I have to be in Washington, D.C. on March 13th at the meeting of the Judicial Conference of the United States, which is the governing body for the federal courts. I'll get back that night. So we could start on the 14th and miss a day, which would be my intention. If we could miss two days, there's

other meetings on the 14th that I don't have to be at but it would be helpful. Which means we'd start on the 15th.

I guess my question to you is if we do three weeks of trial four days week, that's 12 days of trial total. As I mentioned before, I do five and a half hours of trial time a day.

Can we lose a day or two at the beginning or is that going to create problems? I'll tell you at the end I have no availability. The week after we end trial I'm out of town all week in rules committee meetings.

MR. LOPEZ: I missed that, Your Honor, that last thing that you just said.

THE COURT: I have no flexibility to push it into April. The first week of April I've got meetings out of town all week. So we've got to do it in March. Which means if we start on the 14th or 15th we're compressing the time.

MR. LOPEZ: I don't want -- I don't have a calendar. Is there a day beyond that last day you have that's still March? I don't know.

THE COURT: No. Trial would end on Friday, March 30th, and I'm out of town on Monday, April 2nd. So there's -- we've got to get the case concluded by Friday, March 30th.

MR. LOPEZ: Mr. O'Connor's going "we can do it, we can do it." I think we can live with that, Your Honor. I'd

rather keep that and discipline ourselves to squeeze it in to one less day.

MR. NORTH: Certainly, Your Honor, I think as long as the time, of course, is split evenly, which I know it will be, we'll be fine.

MR. LOPEZ: We may get a couple more hours; we get rebuttal.

THE COURT: Okay. So we'll start the trial on March 14th. I'll come back on the evening of the 13th, American Airlines willing.

On the hours point, as I think I might have mentioned to you before, I allocate hours and I keep track of them. I tell you at noon each day and end of the day how much time you've used so you can budget your time.

Typically when I divide time between plaintiffs and defendants, because plaintiffs have the burden of proof I give plaintiffs a couple more hours than I give defendants. So that would be my intent, to take these remaining days and allocate it in that way. Are there any concerns about that?

MR. LOPEZ: No, Your Honor.

MR. NORTH: None, Your Honor.

THE COURT: You mentioned in your joint report a jury questionnaire.

MR. O'CONNOR: We filed those this morning. I have copies for you, Your Honor. We have a joint set we agreed to

and then we filed a separate set where we couldn't reach agreement on part of the plaintiffs.

THE COURT: That's been filed?

MR. O'CONNOR: Yes. I have copies for you, if you like.

THE COURT: Okay. You can leave them with Traci. I'll look at those next week. We have to decide if we're going to do it. If we're going to do it we've got to get it out mid-January, I think, Traci? So it's not something I can sit on very long.

THE COURTROOM DEPUTY: Yes.

THE COURT: I will look at it. If I think we need to talk over whether or not we ought to do it I'll get you on the phone so we can get it decided in time to get it out if we're going to use it.

MR. NORTH: Your Honor, we sort of resolved most of this last night as far as how we were going to submit it and we haven't had the time to prepare formal objections to the questions we couldn't agree upon. If the Court needs us to we can. If not, we're fine.

THE COURT: You don't need to.

MR. NORTH: Thank you.

THE COURT: In a three-week trial I would sit an eight or nine person jury so we can lose two or three and still have enough for verdict at the end. If the flu season

continues to progress as it has, I'll probably seat nine. Is there any concern about that? And the reason I ask that is that will influence my thought on jury questionnaires and how long it will take us to pick a jury.

MR. LOPEZ: We're okay with that, Your Honor.

MR. NORTH: Certainly, Your Honor.

THE COURTROOM DEPUTY: There's nothing on the docket about jury questionnaires.

THE COURT: There's been no jury questionnaire put on the docket yet, so you might want to make sure it got filed.

MR. LOPEZ: Not to take back what I said earlier about the time, but might there be times in that three weeks if we needed -- maybe I should ask this outside of the presence of your staff, but where if we needed an extra hour we can start early, end maybe an hour early.

THE COURT: Yeah, I'll try to be flexible. The limiting factor, in addition to our physical energy, is all the other cases that we've got. And when I'm in trial I tend to schedule hearings starting at 4:00 and 4:30 at the end of the trial day because I've got to do hearings during those weeks. But, yeah, I'll try to be flexible. If we need to start a little earlier some days, like 8:30, we can work with that.

THE COURTROOM DEPUTY: We found the questionnaires.

THE COURT: Okay. We found the questionnaires.

They're on the docket.

All right. Let's take a break for the benefit of Tricia and then come back and talk about the motion to exclude Kinney, Roberts, and Kalva, and the motion to certify the preemption ruling, and any other matters you want to take up. We'll come back at quarter after 3:00.

(Recess taken from 3:02 to 3:15.)

THE COURT: Defense counsel -- plaintiffs' counsel, I forgot to ask this during the earlier discussions, but it's a matter I'm curious about. In the joint report for today's hearing, you indicate that you want to file a motion under the *Cisson* case, C-I-S-S-O-N, which I infer would be a motion saying I should preclude Bard from talking about the FDA?

MS. REED ZAIC: Yes, Your Honor. Well, two aspects of it, Your Honor. The 510(k) clearance process and any evidence suggesting any lack of follow up or enforcement by the FDA.

THE COURT: And if I were to grant that motion would Dr. Kessler and Dr. Parisian become irrelevant?

MS. REED ZAIC: Unfortunately, because of flights, my two colleagues that could probably better answer that are no longer here, so I'm not prepared to say they're not completely relevant, but obviously relevance with regard to FDA would be limited.

THE COURT: If I granted that motion, I'm assuming

the plaintiffs would be agreeable that you don't mention the FDA warning letter.

MS. REED ZAIC: I believe, Your Honor, I believe so. With regard to follow up and enforcement it would seem to come under that, but I would have to give that some more thought.

THE COURT: I assume you don't put Kay Fuller on the stand to talk about her concerns with FDA compliance?

MS. REED ZAIC: Again, I'm not prepared to give an absolute on that, but any premarket activity would seem less relevant, Your Honor, absolutely.

THE COURT: And why is it you think we should be filing or hearing that motion now?

MS. REED ZAIC: I believe that it would be more efficient for the parties to have that ruling now, Your Honor, because with regard to preparing deposition cuts and things like that, pretrial preparations, we would have a better sense of the scope of the evidence and order of proof.

THE COURT: Okay.

MS. REED ZAIC: Gives us more time, Your Honor. And, again, I believe in the joint statement we included the plaintiffs would be ready to file that relatively immediately, and the only request, which I believe was a joint request, is some additional pages, which I believe the plaintiffs could make that motion, and I know Your Honor prefers three pages, I think we can probably do it in eight.

THE COURT: Okay. Mr. North, you were going to say something on this?

MR. NORTH: No, Your Honor, I don't think so.

THE COURT: Do you agree getting that issue decided sooner rather than later would be a good idea?

MR. NORTH: It might make our jobs a little bit easier when it comes to deposition cuts and things of that nature, but I worry about trying to expedite a motion with everything else on the Court's plate. I think that's your choice because it is a meaty motion and there are obviously about ten more *Daubert* motions to be decided at this point.

THE COURT: Okay. Let's talk about the motion to exclude Kinney, Roberts, and Kalva.

MR. NORTH: Your Honor, my colleague, Matt Brown, is going to address this motion.

MR. BROWN: Thank you, Your Honor.

Given what you've said previously about some issues that you've already thought about, I was going to limit the motion to just a couple of issues that I think may be helpful for the Court.

THE COURT: Okay.

MR. BROWN: The first being Dr. Kinney, Roberts, and Kalva's reliance on the reports of Drs. Kessler, Betensky, and McMeeking, which we think should be excluded under two independent grounds, the first under Rule 703 and the second

under Rule 702.

Taking Rule 703 first and reliance on these litigation consultants' opinions, Dr. Kessler, Betensky, and McMeeking, whose opinions were formed solely for purposes of this litigation, under Rule 703 it's the plaintiffs' burden to be able to prove that experts other than Drs. Kinney, Roberts, and Kalva would rely and act upon those litigation consultants' opinions for matters other than litigation.

THE COURT: Let me -- let me ask you a question on that.

If I look at the language of Rule 703, the first sentence says, "An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed," period.

That would seem to include a report from Dr. Kessler discussing facts in the case.

The part you're relying upon says if experts in a particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted.

It seems to me the requirement that facts be the kind that an expert relies upon in a particular field only applies if they're inadmissible. Do you agree with that?

MR. BROWN: I don't agree with that, Your Honor. And looking at Judge Weinstein's treatise on this rule --

THE COURT: I've read his treatise. He doesn't address this issue.

MR. BROWN: We do identify it in our -- I believe it's the reply brief. But it's Judge Weinstein's treatise, he writes, quote, Rule 703 is concerned with the trustworthiness of the resulting opinions. The proponent of the expert must establish that experts other than the proposed witness would act upon the information relied upon and would do so for purposes other than testifying in a lawsuit. And that's really the heart of the issue.

And in addition, Your Honor, the Central District of California addressed this issue in In Re Imperial Credit Industries Securities Litigation in 2003, and in that case there was the accountant who was needing to provide a residual evaluation opinion for a securities case and he relied upon an expert's report filed in another case related to a residual evaluation --

THE COURT: I read that case. That seems to me to be a different problem because what he -- the accountant was taking the valuation that another expert gave and using it as the valuation in this case and the court said you can't do that, you didn't form that valuation opinion.

MR. BROWN: Yes. That goes to the other issue, which is under Rule 702. But specifically Central District of California excluded that opinion under Rule 703 because it was

an expert -- an expert opinion formed for litigation and that is something that's not appropriate to rely upon under Rule 703.

And that's the same issue here, which is that Drs. Kessler, Betensky, and McMeeking formed their opinions specifically for litigation and interventional radiologists would not be relying on that type of information generally in their private practices and there's been no evidence in the record to suggest otherwise.

The plaintiffs cite several portions of Dr. Kinney's deposition in their response. That doesn't bear on the issue. And then they make an unsupported assertion of counsel that interventional radiologists would have welcomed this additional information, which we don't think is sufficient under Rule 703.

THE COURT: Well, doesn't this happen all the time in cases? For example, I had a case where a tire defect expert opined that the tire was improperly designed, was defective and dangerous, and then I had a separate industry standard expert who said assuming it's defective, I will assume it's defective as the first expert said and, if so, there should have been disclosures. Are you saying that second expert couldn't rely upon the first expert to establish the defect for purposes of his opinion?

MR. BROWN: I think that that's an issue the parties

could raise, certainly, whether an opinion that's formed specifically for litigation is something that can be relied upon.

Now, if that second expert is relying on the first expert's opinion-considered material other than that initial expert's opinion in forming his opinion, then that may be something that the expert could do under Rule 702, which is what we get to next with Drs. Kinney, Roberts, and Kalva.

Under Rule 702 we think that Drs. Kessler, Betensky, and McMeeking should not be able to have their reports relied upon by Dr. Kinney, Roberts, and Kalva because under multiple decisions within the Ninth Circuit and Central District of California the discussions about an expert relying upon opinions of others if other evidence supports the opinion and the record demonstrates that the expert undertook an independent evaluation of that evidence. And the record here suggests strongly that there was no independent evaluation of the evidence that Drs. Kinney, Roberts, and Kalva performed.

THE COURT: Let me interrupt you one more time. What I have understood those cases to mean is that the second expert cannot testify to the opinion of the first expert as though it's the second expert's opinion unless the second expert did the work necessary to form the opinion. For a whole host of reasons.

Is that what you think Kinney, Kalva, and Roberts are

doing here?

MR. BROWN: That's exactly what we think they're doing and the record, I think, supports our thoughts on that process. Dr. Kinney testified repeatedly at his deposition the primary source that he used to write the first 110 pages or so of the Rule 26 report was Dr. Kal- -- Dr. Kessler's report, rather, and that --

THE COURT: Was he saying "I looked to Dr. Kessler's report to develop the factual basis upon which I now state my interventional radiologist opinion?" Or was he saying "Dr. Kinney opined to Proposition A and I'm opining to Proposition A"?

MR. BROWN: It's a mixture of both, Your Honor. There are large portions of the reports of Drs. Kinney, Roberts, and Kalva that are copied and pasted from the report of Dr. Kessler.

For example, beginning portions of the Rule 26 report, Dr. Kinney writes that Dr. Kessler said so-and-so and provides a long block quotation and says we fully endorse that opinion. Similarly -- and they go on and make similar long block quotes of Dr. Kessler, Betensky, and McMeekings reports.

THE COURT: If we were in trial and Dr. Kinney was attempting to do that on the stand and said "Let me describe to you jurors now the ten paragraphs Dr. Kinney wrote on this subject" and started reciting, I'd sustain that objection in a

hot second because he can't be the mouthpiece for Dr. Kessler.

I can understand why they might do it in a report, so that they're disclosing to you what he took into account in forming his separate opinions. Clearly he couldn't do it at trial.

If that's a correct statement of the law, then is there a basis for excluding what Kinney could testify from his own expertise?

MR. BROWN: I think so, Your Honor, because the issue is does Dr. Kinney have the baseline level of information that he evaluated in forming his opinions as expressed in the Rule 26 report that he arrived at independently after his independent evaluation, and the answer to that is no. All he did was review the reports of Dr. Kessler, largely, followed by Dr. Betensky and Dr. McMeeking.

The Facts and Data Considered list of their Rule 26 reports list only 42 internal Bard documents and all but two of those documents are also identified in other experts reports, principally Dr. Kessler's report. Dr. Kinney also testified in his deposition that he didn't even read all 42 of those internal Bard documents because he relied so heavily on Dr. Kessler's report and that material was provided to him as, quote/unquote, backup material. We think that is what the key issue is. Drs. Kinney, Roberts, and Kalva also identify a number of depositions they reviewed but, again, Dr. Kinney

said that material was backup material and there's not been any type of showing by the plaintiffs in the response brief as to how that deposition material independently supports the opinions that Drs. Kinney, Roberts, and Kalva arrive at as identified in their Rule 26 report.

Turning now to the second issue which I think may be helpful for the Court is this issue of informed consent and what a reasonable physician would want, how a reasonable physician would think, and how a reasonable physician would act and we think those opinions should be excluded under Rule 702 because they're not based on any objective standards but, rather, their just the ipse dixit of Drs. Kinney, Roberts, and Kalva.

This presents a classic joiner issue for the Court and something that the Ninth Circuit has addressed in the post-*Daubert* remand where they wrote, quote, We've been presented only with the experts' qualifications, their conclusions, and their assurances of reliability. And under *Daubert*, that's not enough. But this is exactly what Drs. Kinney, Roberts, and Kalva are purporting to offer the Court and the jury with regard to what a reasonable physician would think, how a reasonable physician would act, if provided additional information from Bard.

This fails every *Daubert* factor that we have. There's no methodology that they've identified to arrive at

those opinions, there's no scientific principle to support their opinions, other than informed consent, which I'll get to in a moment. The opinions haven't been tested, there's no known rate of error, they haven't been peer reviewed, there is nothing to suggest the opinions they provide are generally accepted in the community of interventional radiologists.

What they do is point to an informed consent document entitled ACR SIR Practice Parameter on Informed Consent for Image Guided Procedures, which we attached as Exhibit D to the reply brief as their, quote/unquote, scientific principle to get over the 702 hurdle. We think this is a red herring for several reasons. First is that informed consent is strictly a medical malpractice concept. It's a different issue, there's a different legal test than what constitutes a duty in a failure to warn case, which is what's left in Ms. Booker's case, for example.

In the plaintiffs' response brief, they go on at length about the informed consent process and the informed consent doctrine and why it's important. But notably absent from that lengthy discussion is a single case that discusses informed consent in the context of a product liability failure to warn case.

Secondly, if you look at the guidance documents Drs. Kinney, Roberts, and Kalva cite, it's a guidance document that talks about the informed consent process, not the

informed consent content. And it's an important distinction because the language of the guidance document itself as it pertains to risks says physicians should inform patients about, quote, the risks, complications, and expected benefits or effects of such procedures or treatment, close quote.

But there's nothing in that guidance document that speaks to what is sufficient to satisfy that informed consent process.

For example, does a risk of 0.1 percent need to be disclosed to a patient? What about 5 percent? Or 10 percent? The guidance document simply doesn't say, and so Drs. Kinney, Roberts, and Kalva are using this process related informed consent document as a vehicle to put their personal opinions about what is sufficient to arrive at an informed consent process before the jury. We think that that is not appropriate because it's not based on any type of objective standard. They're simply saying, well, this is what we think having looked at this document and looked at the material that we've been -- received from Bard.

And finally, you alluded to this at the beginning of today about the long string cite that we provide in the motion as relates to the informed consent doctrine. The three most important decisions there are the Rezulin case from 2004 from the Southern District of New York and the two in re diet drug MDL decisions from the Eastern District of Pennsylvania from

the early 2000s.

The courts there confronted a very similar issue where the experts for the plaintiffs purported to say that had physicians across the country had additional information from the manufacturer, they would not have prescribed Rezulin, for example. And the courts in those cases said that that is impermissibly speculative, you can't do that under Rule 702, those are personal opinions, they're not reliable, and you can't make them.

The plaintiffs don't say a thing about any of those decisions in the response brief.

The remainder of the long string cite is a CF citation where we're citing to additional cases where the courts have said you need some type of objective standard to be able to offer opinions to the jury.

Unless the Court has any specific questions about the other portions of the motion, that's all I wanted to address with you.

THE COURT: Okay. Thank you.

MR. BROWN: Thank you, Your Honor.

MS. O'LEARY: Good afternoon, Your Honor. I'm Leslie O'Leary. I think I've been before you one time in a pain pump case, other than that I'm new here.

I would like to address the reliance on other experts argument. I think I can make it a little bit clearer what

happened.

In our response brief we did present testimony by Drs. Kinney and Kalva and Roberts saying in addition to reading the reports of these other experts, they also looked at their underlying documents, all their references, too, and so that's part of the record.

To make it clear, the plaintiffs' counsel provided them a Dropbox database and it included not just the reports but all of the references. So if they wanted to look up a reference to Dr. Kessler's report at page -- at paragraph 55, they could click on that and have all the documents. So that's what they did. They looked at the documents that supported their opinions.

In fact, they reviewed a lot of them. Dr. Kinney said in addition to looking at all of the medical literature which he pulled and reading the 510(k)s and studies supporting the 510(k)s for these devices, he also looked at the underlying references in these reports.

So when you look at the cases the defendant cited saying that these are the examples of how experts are not allowed to rely on other experts' reports and testimony, those cases made exceptions where, and I think you pointed this out, Your Honor, where they're not just basically adopting wholesale their reports and acting as their mouthpiece but they actually looked at the underlying data to make sure it

was coherent with what they were saying. So they did rely on all of that.

Unfortunately, their List of Facts and Data Considered list was only the documents that they referenced in their reports. They actually looked at a much larger collection than that. So I just wanted to make that clear, that they aren't just blindly looking at reports and just accepting them at face value. They actually did look at the documents supporting them.

THE COURT: I read the deposition sections you cited. It seemed to me the one exception to what you just said was Dr. Roberts. She said, I looked at some of the documents that Kinney cited -- or Kessler cited to satisfied myself that he was being accurate. That's all she really said, I think.

MS. O'LEARY: And her role in drafting the report itself was a little bit different because she didn't actually do the drafting. She worked with the other experts and she reviewed what they said and went back and fact checked and looked at the underlying documents and things like that, but she wasn't actually writing the report itself.

But one thing that's interesting is that defense experts had testified that they had looked at Dr. Kessler's report and Dr. Kinney's, Roberts', and Kalva's reports and were asked if they looked at any underlying documents, just to make sure that the factual basis for their opinions were

correct, and these -- I think it was Dr. Moritz said, Oh, I did look at them. I looked at both of their reports, and they were so detailed that I had no question to -- no reason to question the factual basis for them.

And I think what happens to make -- I think these other cases the defendants relied upon had a major concern which was the factual basis for the reports they're relying on might be unreliable. But if defense experts don't have any basis to question that and if Dr. Kessler's underlying facts are reliable, then we're not looking at something that's shady or irrelevant to begin with.

So this is just a huge compilation of factual data that they did look at. They didn't -- they didn't ignore it. They had a lot of it that they sifted through. Unfortunately, they didn't keep track of what they looked at and decided not to include in their reports versus what they just glanced at. But they did look at a tremendous volume of data, and also looked at expert -- at employee witness depositions and their underlying documents. So they had a big trove of materials that they looked at and then they culled them down when they wrote their report.

So the bottom line is this really comes down to the factual basis for their opinions, which is more a matter of cross-examination than it would be for exclusion.

In terms of reasonable expectations, the standard of

care they articulate, I think that the defendants have raised -- they seem to express confusion over informed consent.

Counsel had talked about how informed consent is really an individual judgment not a collective one. But there are two sides to informed consent, and I think they're confusing what the manufacturer must disclose to the physician versus what the physician has an obligation to disclose to the patient.

So there's two parts of the equation. There's how does a physician become informed enough to give -- obtain informed consent from the patient and so it's the first part of the equation that Drs. Roberts, Kalva, and Kinney are talking about. They're not talking about what they would have done or what any particular individual physician would have done with that information. That's more of a question that would come up at trial. That's more of a causation question. The question is what is the type of information that physicians in this field of interventional radiology need to know in order to do what these experts do.

They train their colleagues on how to insert these devices, the types of patients they're indicated for, under what circumstances certain types of these filters should be used. It's that body of information they need to be able to inform themselves and help inform their colleagues and then

inform their patients and make that decision. But it's really hard to get proper informed consent if you're not informed.

So that's -- that's the -- that's the first half of the informed consent equation that they're offering their expertise in.

And it may very well be that an informed physician may decide in light of all of the information on all of the complication rates and everything else, might decide in a particular patient, you know, I know all of this but I'm going to recommend putting this filter in any way, and that's an individual judgment. And -- but that's not what we're talking about here. These experts aren't going to come and talk about what I would have done with my individual patients. They're saying this is the information we rely on because otherwise we lack the ability to do our jobs as physicians and give our patients important information that they would want to know.

So that's where they're coming from. And there's also similar confusion over this learned intermediary doctrine. The defendants in their reply brief cited *Fields versus Eli Lilly*, which is a Ninth Circuit decision, and they're saying this really -- that it really has to do with, well, had I gotten that information what would I have done with it?

Again, we're talking about the duty to give adequate information, the duty to warn the physician first. That's a

duty and a breach question, and that's what the experts are here to talk about. Whether or not -- what an informed physician would have done with that information is a causation question and our experts aren't here to testify about causation.

This is not a make believe standard that the experts have come up with. The sources of this are implicit in their SIR guidelines that we -- that they had mentioned informed consent for one thing. They explain that the patients have to have every opportunity to fully understand the treatment and procedure and its reasonable risks. But those patients won't get the informed consent they need unless physicians get the information they need to fulfill their obligations.

So, again, it's the first side of the equation, not the second side of the equation.

Another source is their quality improvement standards that the SIR developed, and they've developed these for other physicians. It wasn't developed for manufacturers, but it was basically to help them determine when and how to use these filters and under what circumstances based on the information they had available to them from the manufacturers and all of the studies.

But they also issued publications and articles strongly encouraging manufacturers to come forward and do studies, more studies were needed, because there isn't enough

to be able to compare the safety and efficacy of all these different filter types.

So the statement that was in these SIR guidelines that these weren't intended to establish legal duties of care was directed at the second step of that informed consent which is we're not meaning these regulations or these standards to be duties of care to determine the liability of a physician who makes a decision on behalf of one particular patient. It was never intended to be that way. So that cautionary note is really irrelevant to the discussion.

Another source of this reasonable expectation, this duty of care to interventional radiologists and cardiologists is from Bard's own internal documents. We had cited this in our brief, but basically Bard had put -- had brought together a group of physicians, interventional radiologists and cardiologists and said, hey, what do you think about the design of our products? And they came away with the understanding that these doctors insist on knowing what the failure rates are of their devices and they need to know if there's any problem with them, that there's zero tolerance for complications that arise and they need to know about them.

Another source of this is from Bard's own employees. They testified that of course physicians have a reasonable expectation that they will be informed of any risks or complications as they arise. And so they were -- they were

aware of that. That was something that they adopted.

In addition, defendants' own experts have articulated this standard. Dr. Feigal, who's one of Bard's experts, actually published an opinion piece in the New England Journal of Medicine, and this was basically about the importance of forthcoming and honest of disclosure of risks and complications of implantable cardiac devices. And he stated from the perspective of physicians and patients' expectations, corporate responsibility and public perception, we believe active communication policies centering on the proper use of active and passive transparency should be the norm. So this is a statement that just wasn't drawn out of thin air.

I'd also like to address the criticism that defense raises about the reliability under Rule 702 of this standard. They basically attack it because it doesn't meet the four *Daubert* criteria, but the case *U.S. v Hankey* really addresses this issue and it's when an expert's testimony isn't based on a scientific principle but on their own experience and knowledge. Then these *Daubert* factors are not really applicable. The four *Daubert* criteria are helpful but when the reliability depends on the knowledge and experience of the expert rather than methodology behind it, then those factors don't come into play so much.

I might add that this duty to warn, this standard of care is consistent with other duties and concepts in common

law. It's certainly similar to the duty under FDA regulations to adequately inform physicians -- adequately inform the FDA and also prescribing physicians, but, again, under learned intermediary and informed consent doctrines this duty to be forthcoming and provide relevant material information is entirely consistent with this duty of care. And it's not simply a medical malpractice standard. This is a standard that I've had cases involving what -- you know, what a physician would expect under the circumstances, what they expect to be told.

So this isn't something that is ipse dixit, it's a duty that common law and that imposes on any manufacturer, any reasonable manufacturer, to convey information that is important to their practice.

So these experts testimony on the standard of care provide a helpful framework for the jury to decide in determining whether Bard breached its duties of care in disclosing important safety information about the complications and so Bard's criticism of that is best left to cross-examination but not exclusion.

THE COURT: Okay. Thank you.

MS. O'LEARY: Any other questions?

THE COURT: No. Thank you.

MR. BROWN: Your Honor, I think we've adequately responded to all of the points that plaintiffs' counsel made

in our reply brief.

THE COURT: All right. Thank you.

Counsel, let's talk about briefly the motion to certify the preemption ruling. And I'd like to address it to Bard, particularly in light of a couple of facts that you may already be aware of.

This week I received two Ninth Circuit rulings on decisions I had made. One I made in September of 2014, second I made in April of 2015. Two and a half plus years.

I certified -- I had a big securities fraud class action. I certified the class but then came upon a loss causation issue that was very confused in Ninth Circuit law. I certified that issue to the Ninth Circuit in August of 2015, telling them that I wasn't going to hold trial until I knew what the -- actually, depending which way they went, I would either grant summary judgment or not and we were going to hold off until they answered. I still don't have a decision. That was 28 months ago. And they took it. They took it within a month. I thought great, we'll get a quick decision. 28 months and nothing.

It's not unusual. I had a case recently that was a 2013 decision that was just affirmed.

I am confident if I certify this issue to the Ninth Circuit, we will be here two or two and a half years from now -- well, I don't know if we will be, but it will be two or

two and a half years before we get a decision. That's just unfortunately the workload they face and the pace at which they get things decided.

I don't know how much that affects -- and there's one other question I'd appreciate your thoughts on, Mr. North, is if the jury in the Booker case or the Jones case were to rule against Bard, presumably I enter a judgment, you appeal and that takes with it the preemption motion so it would get there then as well. Obviously, if you win at those two cases, that wouldn't be situation.

In light of those Ninth Circuit realities, would you tell me why you think it's a good idea to certify the matter.

MR. NORTH: Well, I was not familiar with that sort of backlog, Your Honor.

I would recognize, based on what the Court has reported, that is a risk and probably a substantial risk. With all due respect to this Court, my client is determined to present this case -- issue at some point to the U.S. Supreme Court and invite that court to address the very problems in this area of the law that then-Judge Gorsuch mentioned in the *Caplinger* case. The question is how do we get there.

We're not asking, of course, for any stay of proceedings in this court. We recognize that's not a prudent thing to do with an MDL of this magnitude. But what we are looking for is what avenue we pursue this issue -- again, with

due respect to the Court's ruling -- up to the U.S. Supreme Court.

THE COURT: It doesn't bother me you want to appeal it.

MR. NORTH: Okay. Thank you, Your Honor.

THE COURT: I could have guessed that you disagree with the decision. That's fine.

MR. NORTH: I once clerked for an Eleventh Circuit judge who didn't have that same view necessarily, I'll just say that.

And what I'm concerned about, too, is given the nature of an MDL, and I think that's why a lot of cases have said 1292(b) appeals are so important in the MDL context -- for example, we can find ourselves pursuing this issue in a number of circuits, to be honest with you. I think three of the mature cases are in Florida and Georgia. So if those were to be remanded at some point this year and tried, we would either -- could have an appeal if we lost or a cross-appeal if we won and they appealed, raising that issue in front of the Eleventh Circuit.

There are a couple cases in the Fifth Circuit.

It's -- we are going to pursue this case, or intend to pursue this issue in whatever forum we first receive the opportunity to.

I would submit to the Court that, while recognizing

the realities of what the Court said and what's happened before, that we could at least try with the Ninth Circuit. As opposed to trying to piecemeal it. And it may be a race to see which case court addresses the issue first, appellate court circuit, and it ends up in the Supreme Court or on a certiorari petition to see if that court is interested in reviewing it.

But I guess what I'm thinking, even though I understand the impediment the Court says as far as timing, I don't know that I see a negative in at least presenting it to the Ninth Circuit since it's not going to stay proceedings here. Maybe this is one of those times they move quickly. Who's to say.

THE COURT: Okay, I understand that. There's also the question of whether I think reasonable jurists could disagree. But I understand your argument on that, particularly in light of the Tenth Circuit decision from Justice Gorsuch.

Plaintiffs, did you want to saying anything on this motion?

MS. REED ZAIC: Your questions were addressed to the defense. We have nothing additional to add to our papers.

THE COURT: That covers everything on my list. Do you all have matters you want to take up before we break?

MR. O'CONNOR: I think we covered everything. I

think on plaintiffs end we're good, Your Honor.

MR. NORTH: Nothing further for the defense, Your Honor.

THE COURT: Okay. Thank you all. Have a great holiday. We'll see you in January.

MR. NORTH: Thank you, Your Honor.

MR. O'CONNOR: Thank you, Your Honor.

(End of transcript.)

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C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 17th day of January, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter